A PROSPECTIVE OPEN LABELED RANDOMISED CLINICAL TRIAL ON THANDAGA VATHAM (LUMBAR SPONDYLOSIS) WITH VAEPPAM PATTAI KUDINEER

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BONAFIDE CERTIFICATE

This is to certify that the dissertation entitled **"A PROSPECTIVE OPEN LABELED RANDOMISED CLINICAL TRIAL ON *THANDAGA VATHAM* (LUMBAR SPONDYLOSIS) WITH VAEPPAM PATTAI KUDINEER"** is a bonafide work done by **Dr. L.JENSIN BRINTHA (Reg. No. 321511003)** Govt. Siddha Medical College, Palayamkottai in partial fulfilment of the University rules and regulations for award for **MD(S), BRANCH-I POTHU MARUTHUVAM** under my guidance and supervision during the academic year **2015-2018.**

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DECLARATION

I declare that the dissertation entitled **"A PROSPECTIVE OPEN LABELED RANDOMISED CLINICAL TRIAL ON *THANDAGA VATHAM* (LUMBAR SPONDYLOSIS) WITH VAEPPAM PATTAI KUDINEER"** submitted for the degree of MD in Siddha Medicine of Government Siddha Medical College, Palayamkottai, Tirunelveli, Tamil Nadu (The Tamil Nadu Dr. M.G.R. Medical University, Chennai) the record of work carried out by me under the supervision of **Prof. Dr.A.Manoharan, MD (S), Ph.D.,** Head of the Department of Pothu Maruthuvam, and guidance by **Dr. T. Komalavalli, MD (S), Ph.D.,** Associate Professor, Govt. Siddha Medical College, Palayamkottai. This work has not formed the basis of award of any degree, diploma, associateship, fellowship or other titles in the university or any other university or institution of higher learning.

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LIST OF ABBREVIATIONS

%	-	Percentage
ALT	-	Alkaline Phosphatase
ANOVA	-	Analysis of Variance
AS	-	Ankylosing Spondylitis
ASO	-	Anti-Streptolysin 'O' Factor
B_1 gene	-	Beta 1 gene
Bid	-	Twice a day
BMI	-	Body Mass Index
BPFS	-	Back Pain Functional Scale of Stratford et al
CT	-	Computerized Tomography
cm	-	Centimeter
CRP	-	C-Reactive Protein
DC	-	Differential Count
dl	-	Decilitre
E	-	Eosinophilis
EMG	-	Electromyography
ESR	-	Erythrocyte Sedimentation Rate
gms	-	Grams
Hb	-	Haemoglobin
HDL	-	High Density Lipoprotein
i.e.,	-	That is
IVD	-	Inter Vertebral Disc
JVP	-	Jugular Venous Pulsation
kg	-	Kilo Grams
L	-	Lymphocytes
L_5-S_1	-	5^{th} Lumbar Vertebrae upto first sacral vertebrae
mg	-	Milligrams
ml	-	Milli Litre
mm	-	Millimeter
MRI	-	Magnetic Resonance and Imaging
MS	-	Multiple Sclerosis
NPRS	-	Numeric Pain Rating Scale

^{o}	-	Degree
ODI	-	Oswestry Disability Index
OPLL	-	Ossified Posterior Longitudinal Ligament
P	-	Polymorphs
PSEQ	-	Pain Self-Efficacy Questionnaire
PSFS	-	The Patient-Specific Functional Scale
RA	-	Rheumatoid Arthritis
RBC	-	Red Blood Corpuscles
Ref	-	Reference
RMDQ	-	Roland Morris Disability Questionnaire
SAP	-	Superior Articular Process
SEM	-	Structural Equation Modelling
SLE	-	Systemic Lupus Erythematosus
SLR	-	Straight Leg Raising
SPECT	-	Single Photon Emission Computed Tomography
T_9-T_{10}	-	9^{th} Thoracic Vertebrae to 10^{th} Thoracic Vertebrae
TC	-	Total Count
U/L	-	Units per Litre
WBC	-	White Blood Corpuscles
WHO	-	World Health Organisation
TC	-	Total Cholesterol
OECD-423	-	Organisation of Economic Co-Operation and Development
LD	-	Lethal Dose

ABSTRACT

Low backache (Lumbago) is one of the most common illness faced by most of the people in their day to day life. It's etiology varies widely like heavy weight lifting, long travelling, adapting in appropriate postures, vertebro spinal injury, age related degenerative changes etc. Low back pain which is the chief complaint of ***Thandaga Vatham*** is mentioned in Siddha text book ***Yugi Vaidhya Cinthamani-800.*** The clinical features of Lumbar spondylosis has become a major problem in day today life, despite of many advances in treatment. Conventional medicines and surgical treatments end up with side effects and leave with defect and detriment like recurrence of pain, disability & nerve root damage.

This study is concerned with 'A Prospective open labeled randomised Clinical trial on ***Thandaga Vatham*** with Vaeppam pattai Kudineer' medicine evidence is described in ***Gunapadam Mooligai Vaguppu Part-I*** text book. Totally 40 patients with ***Thandaga Vatham*** (20 In patients, 20 Out patients of both sex) were selected randomly from OPD of Pothu Maruthuvam, Govt. Siddha Medical College, Tirunelveli, Tamil Nadu. They were given Vaeppam pattai Kudineer 50ml twice a day for 30 days. After the course of treatment majority of cases showed good response which is statistically significant.

Keywords:

***Thandaga Vatham*, Lumbar Spondolysis, Vaeppam Pattai Kudineer, Cardinal Signs, Range of motion, Back Pain Functional Scale Score (BPFSS).**

CHAPTER-I

INTRODUCTION

Siddha system is one of the ancient system of medicine flourished in southern part of India. It helps to lead our day to life under the influence of traditional culture and disciplined food habits for healthy living. Siddha system provides ways of curing many chronic diseases like auto immune diseases and non communicable diseases.

According to the basic concept of siddha system, man is viewed as a micro cosm and the universe as a macro cosm. Principles present in macro cosm can be find in micro cosm and vice versa. In other words, man is a miniature of universe. The universe in turn is constituted of five primordial elements (i.e.,) earth, water, fire, air and space, it is called Panchabootha Pancheekaranam.

These five elements, five combinations possess two properties viz., subtle (sookumam) and gross (sthoolam). These elements always act in mutual co-ordination and can never act independently. The various proportions in which they combine give rise to different substances. Thus, this theory proposes that 96 basic factors (Thathuvangal) exist, which is the basic concept underlying this holistic medical science.

The human body formed by these 96 basic factors is conditioned mainly by:

1) Uyir thathukkal (also called Trithodam or Mukkutram) are the three vital humours, viz., Vatham, Pitham and Kapham.
2) Udal thathukkal are the seven physical constituents.

The foretold 96 factors are the physical, physiological, psychological, intellectual aspects of every human. The five primordial elements manifest themselves as a human with these 96 basic factors.

"உருபொருள் தாங்குமுடலு முயிரும்
உடற்காதார மொன் பஞ்சபூதப்
பஞ்சீகரணப் பான்மையா மெனவும்
உயிர்க்காதார முயிர்த்தாதெனவும்
முப்பிரிவாகி முக்குணமணுகி
உடலையுமுயிரையு மோம்பிக்காத்து
வருமென முதுமறைவகுக்குந் துணிபே"

- நோய் நாடல் நோய் முதல் நாடல்
(பாகம்-I, பக்கம் எண்.78)

The theme of the Siddha system is to place the three humours in equilibrium.

According to **Kuthambai Siddhar** in his poem,

"முப்பிணிதனை அறியாத மூடர்கள்
எப்பிணி தீர்ப் பாரடி - குதம்பாய்
எப்பிணி தீர்ப்பாரடி
நாடியொருபது நன்காய றிந்திடில்
ஓடிவிடும் பிணியே - குதம்பாய்
ஓடிவிடும் பிணியே
சுத்த வகை தாது தன்னையறிந்தோர்
சுத்த வைத்தியனே - குதம்பாய்
சுத்த வைத்தியனே
வாயுவொரு பத்தும் வாய்ந்த நிலைகண்டோர்
ஆயுள் அறிவானடி - குதம்பாய்
ஆயுள் அறிவானடி"

Drugs are classified based on (i) Source of origin, Eg. Thavaram (Plants), Thathu (Metals and Minerals) and Jeeva Products (Animal Products), (ii) Suvai (Taste), (iii) Gunam (Character), (iv) Veeriyam (Potency) (v) Pirivu (Section), and (vi) Mode of usage (32 types of internal and 32 types of external medicines).

We have not touched even the fringe of several esoteric Siddha principles. Yet another interesting part of Siddha medicine is the diagnosis by Envagai thervugal.

So, this study Thandaga Vatham (Lumbar spondylosis), described as a degeneration of the Lumbar vertebrae. In India, Lumbar spondylosis affects 60%-80% of the adults during some point in their lives. 84% of men and 74% of women are suffering from Lumbar spondylosis in the age group of 45-64 years.

Pain in lower back, buttocks, thigh region and it may radiate to foot or toe, numbness, tingling feeling throughout one or both legs and burning sensation in the hips and legs are the symptoms of Thandaga Vatham which can be correlated in modern medicine as Lumbar spondylosis. Details of Thandagavatham is mentioned in ***Yugi Vaidhya Chinthamani-800.*** It is characterized by body ache, generalised weakness all over the body and limbs, yellow coloured stools and yellowish coloured urine, incontinence of urine and faeces, constipation followed by diarrhoea, pain in the nerves, bones and also in the chest and finally inability to walk.

The clinical trial drug **"VAEPPAM PATTAI KUDINEER**" is easily available and low cost in nature. It is easily available as to compare than other drugs. The clinical trial drug Vaeppam Pattai Kudineer has good analgesic, anti-inflammatory activities. It is proven by many pharmacological research works undergone on the constituents, thus justify its potential effect in the clinical study of the management of Lumbar spondylosis (Thandaga Vatham).

CHAPTER-II

AIM AND OBJECTIVES

AIM:

To clinically evaluate the therapeutic efficacy of clinical trial drug in Thandaga Vatham.

OBJECTIVES:

Primary Objective:

- To document the therapeutic efficacy of clinical trial drug in Thandaga Vatham.

Secondary Objective:

- To evaluate the biochemical activity of Vaeppam Pattai Kudineer.
- To determine the safety profile of clinical trial drugs.
- To survey the incidence of the disease, according to Age, Occupation, Habits, Family History, Paruva Kaalangal, Thinai and Three Vital Humours.
- To evaluate the changes in the Envagai thervugal in Thandaga Vatham according to Siddha basic concepts.
- To evaluate the pharmacological activity of Vaeppam Pattai kudineer.
- To do a detailed clinical investigations.
- To collect literary evidence about ‘Thandaga Vatham” disease in detail.

CHAPTER-III

REVEIW OF LITERATURE

a) SIDDHA ASPECTS:

The concept of Siddha system of medicine is based on 96 Thathuvangal which is made up of five primordial basic elements. Among which the three vital humours, Aru suvaigal and udal thathukkal play an important role.

The vital humours are Vatham, Pitham and Kapham. They are also called as Uyir Thathukkal or Thiri thathukkal. They regulate all the physiological activity of the human body.

Vatham is characterised by vayu, dryness, pain, flatulence, sensitiveness, lightness, air and mind.

Pitham is characterised by gastric juice, bile, energy, heat inflammation, anger and irritation.

Kapham is characterised by feeling of cold, heaviness, running nose, secretion of saliva and mucoid discharge in stools and in urine.

When the mutual harmony of the three humours is disturbed, they are called Tridosham (or) Mukkutram and they bring about ill health. This may be due to the alteration in the five basic elements and inturn the 96 Thathuvangal.

Vatham has a vital role in locomotion (or) movement activity. If Vatham is disturbed, locomotion is affected. The other two humours are deranged on severity of disease. Thus in ***Noi Naadal and Noi Mudhal Naadal Part-I*** text book clearly explains about Vatham.

"வாதமாய் படைத்து
பித்த வன்னியாய் காத்து
சிலேத்தும சீதமாய் துடைத்து"

- நோய் நாடல் நோய் முதல் நாடல் திரட்டு
(பாகம்-1 பக்கம் எண்.97)

According to **Sivavakiyar,** Vatham is Omnipotent. It is the beginning, benevolent, soverign, eminent diety. It has the character to regulate two other humours.

"வாதமான தேவனே யாதியாகி நின்றவன்
வாதமான தேவனே வையகம மைத்தவன்
வாதமான தேவனே யறுதொழில் வகுத்தவன்
வாதமான தேவனே வண்மை கண்டு கூறுமே"

- சிவ வாக்கியர் நாடி

The Vatha dosham quoted in various Siddha literature are as follows:

According to **Agasthiyar,**

"காணப்பா வாதமீறில் கால்கைகள் பொருத்து நோவும்
பூணப்பா குடல் புரட்டும் மலசலம் பொருமிக்கட்டும்"

- அகத்தியர் வைத்திய காவியம் 1500
(பாடல் எண்.10, பக்கம் எண்.2)

According to **Theriyar,**

"தக்கவாயு கோபித்தால் சந்துவுளைந்து தலைநோவா
மிக்க மூரி கொட்டாவி விட்டங்கெரியு மலங்கட்டும்
ஒக்கநரம்பு தான்முடங்கு முலர்ந்து வாய்நீரூறிவரும்"

- தேரையர் வாகடம்
(பாடல் எண்.2, பக்கம் எண்.13)

"வாதவீறு அன்னமிறங்காது கடுப்புண்டாம் வண்ணமுண்டாம்
மோதுகட்டுரோகம் சுரமுண்டா மிருமலுமா முறங்காதென்றும்
ஒதுசூரிய வாதமனலாகு நடுக்கமுண்டாம் பொருள்களாய்ந்
தீதெனவே நரம்பிசித்து சந்துகள்தோறும் கடுக்குந் தினமுந்தானே"

- தேரையர் வாகடம்
(பாடல் எண்.210, பக்கம் எண்.58)

According to **Thirumoolar,**

"எறிய நல்வாதம் எறிக்கும் குணங்கேளு
குறியெனக் கைகால் குளைச்சு விலாச் சந்து
புறியென நொந்துடல் பச்சைப்புண் ஆகுமே"

- திருமூலர் கருக்கிடை வைத்தியம்-600
(பாடல் எண்.36, பக்கம் எண்.11)

If Vatham is deranged, the other humours like Pitham and Kapham also gets affected.

வாதமிகு குணம்:

"அறியவிம் மூன்றின் தன்மை சொன்னார்நந்தி
ஏறிய நல்வாத மெறிக்குங் குணங்கேளு
குறியெனக் கைகால் குளைச்சு விலாச்சந்து"

- திருமூலர் கருக்கிடை வைத்தியம்-600

"வாதவீறு அன்னமிறங் காது கடுப்புண்டாம் வண்ணமுண்டாம்
மோதுகட்கு ரோகம் சுரமுண்டா மிருமலுமர முறங்காதென்றும்
ஓதுதரிய வாதமனலாகு நடுக்கமுண்டாம் பொருள் களயர்ந்த
தீதெனவே நரம்பித்து சந்துகள் தோறுங் கடுக்குந் தினமுந்தானே"

- தேரையர் வாகடம்
(பாடல் எண்.210, பக்கம் எண்.58)

"தக்கவாயு கோபித்தால் சந்துளைத்து சூலைநோவா
மிக்க கொட்டாவி விட்டங் கெரியு மலங்கெட்டும்
ஒக்க நரம்புதான் முடங்கு மலர்ந்து வாய் நீரூறிவரும்
மிக்க குளிரும் நடுக்கமாய் மேனி குன்றி வருங்கானே"

- தேரையர் வாகடம்
(பாடல் எண்.43, பக்கம் எண்.13)

வாதம் மிகும் போது பசியின்மை, உடல் கடுப்பு, சுரம், இருமல், உறக்கமின்மை, சுரம் நடுக்கம், நரம்புத் தளர்ச்சி,**சந்துகள்தோறும் குடைதல், விலாச்சந்துகள் நோதல்,** வயிறு பொருமல், குடலிறைச்சல், மலச்சிக்கல், மிகுந்த கொட்டாவி போன்ற குறிகுணங்கள் தோன்றும்.

According to **Yugi Munivar**, place of Vatham is below the umbilicus (Pelvic plexus):

"நாமென்ற வாதத்துக் கிருப்பிடமே கேளாய்
நாபிக்குக் கீழென்று நவில லாகும்"

- சித்த மருத்துவாங்க சுருக்கம்
(பக்கம் எண்.140)

According to **Tamil Maruthuva Sathagam**, poem lines 35, 36 is clearly mentioned asVatham dwells in **Idakalai, Umblical cord, Skin, Joints, Motion, Lower abdomen, Hipbones, Nerves, Hair follicles and Muscles.**

Further, there are 10 types of Vatham, based on their mode of action and location. Vatham is classified into 80 types.

"என்னவே வாதந்தானெண்பதாகும்
....."

- யூகி வைத்திய சிந்தாமணி
(பாடல் எண்.243, பக்கம் எண்.574)

THANDAGA VATHAM is one among Vatha diseases.

THANDAGA VATHAM

SYNONYMS:

தண்டுவாதம், இடுப்பு வாதம் (வாத நோய் மருத்துவம், பக்கம் எண்.114, 126)

DEFINITION:

Thandaga Vatham is a condition, characterized by great prostration, in which the body is rendered like a log of wood, unable to stretch or fold the limb and pass motion or urine. The whole body assumes rigidity similar to the stiffness appearing after death. (T.V. சாம்பசிவம் பிள்ளை, அகராதி பாகம்-IV)

AETIOLOGY:

Any modification (or) disturbances in the uyir thathus, especially in Vatham can result in Vatha diseases.

The factors that play its role in modification of Vatham are,

1) Environmental factors
2) Physical factors
3) Factors of Kanmam

1) Environmental factors (Seasonal Variations):

"ஆடியாதியாய் ஐப்பசிஈறாய்
ஆனிலமதற் கோரரசியல் காலம்"

- சதகநாடி (நோய் நாடல் நோய் முதல் நாடல் பாகம்-I)
(பக்கம் எண்.167, 168)

According to **Sathaga Naadi** the Vatha disease get predominant in the month of Aadi to Iypasi (July to November).

"வாத வர்த்தனை காலமேதோ வென்னில்
மருவுகின்ற ஆனி கற்கடகமாகும்
ஆதவைப் பசியோடு கார்த்திகை தன்னில்
அருடமே....."

- யூகி வைத்திய சிந்தாமணி
(பாடல் எண்.245, பக்கம் எண்.76)

In **Yugi Vaidhya Chinthamani-800**, Vatham is provoked in own site on the month of Iypasi and Karthigai (வேற்று நிலை வளர்ச்சி) and retains normal in the rest of the month (தன்னிலை அடைதல்).

"பதுமத்தைப் பூக்க வைக்கும் பானுமிக்க காயும்
முதுவேனி லிற்பு விநீர் முற்றும் - கதுமென
வற்றும் கபகும் வாயுமிகும் ....."

- மருத்துவ தனிப்பாடல்

மேற்கூறிய பாடலின் மூலம் முதுவேனிற் காலத்தில், சூரிய வெப்பத்தின் காரணமாக பெருவாரியாக நீர் ஆவியாக்கப்பட்டு பூமியில் வறட்சி நிலவும். அதுபோல் நமது உடலில் வறட்சி ஏற்பட்டு வளி நோய் வருவதற்கு காரணமாகிறது.

2) Physical factors:

1). According to **Sabapathy Manuscript,**

"வளிதரு காய்கிழங்கு வரைவிலா தயிலல் கோழை
முளிதரு போன்மிகுக்கு முறையிலா வண்டி கோடல்
குளிர்தரு வளியிற் தேகங்குளிப்புற வுலவல் பெண்டிர்
களிதரு மயக்கம் பெற்றோர் கடிசெயல் கருவியாமால்"

- சபாபதி கையேடு-சித்தமருத்துவம் (பொது)
(பக்கம் எண்.624)

Excessive intake of rhizomes and certain vegetables can increase Vatha diseases. Irregular food intake, prolonged exposure to cold air, staying prolonged in hills area, excessive sexual activity and hereditary factors produce Vatha diseases.

2). According to **Noi Naadal and Noi Mudhal Naadal Part-I,** text

"புளிதுவர் விஞ்சுங்கறி யாற்பூரிக் கும்வாதம்
....."

- நோய் நாடல் நோய் முதல் நாடல்
(பாகம்-I, பக்கம் எண்.23)

Sour and Astringent food stuffs can increases the Vatham.

"மாத்திய புளிப்பு மீறில் வந்திடும் வாதமாகும்
சேத்துமந் தண்ணீர் பித்தந் தீ காற்று வாதமாமே"

(அகத்தியர் நாடி)
- நோய் நாடல் நோய் முதல் நாடல்
(பாகம்-I, பக்கம் எண்.22)

Intake of large amount of sour food can increases Vatham.

"வாதமே புளிப்பு வேண்டும் வன்பித்தங் கசப்பு வேண்டும்
தீதிலாசி லேற்பனந்தான் சேர்ந்திடும் இனிப்பு வேண்டும்
ஓதிய வாத பித்த சிலேற்பன தொந்தத் தோர்க்குக்
காதலாய்த் துவர்த்தல் காரல் உவர்ப்போடு கருதுங்காணே"

(இரத்தினச் சுருக்க நாடி)
- நோய் நாடல் நோய் முதல் நாடல்
(பாகம்-I, பக்கம் எண்.22)

The sour food definitely increases the Vatham while astringent foods are added into it.

3). According to Yugi Muni in **Yugi Vaithya Chinthamani-800.**

"பகரவே வாதமது கோபித்தப்போ
பண்பாக பெண்போகம் அதுதான் செய்யில்
நகரவே வெகுதூர வழி நடக்கில்
நளிரான காற்றுமே பனிமேல் பட்டால்
மிகரவே காய்கள் கனிகிழங்கு தன்னை
மிகவருந்தி மீறியே தயிர்தான் கொண்டால்
முகரவே முதுகெலும்பை முறுக்கி நொந்து
முழங்காலும், கணுக்காலும் கடுப்புண்டாமே"

- யூகி வைத்திய சிந்தாமணி-800
(பாடல் எண்.285, பக்கம் எண்.89)

Excessive sexual activity (or) desire, walking for a long distance, prolong exposure to cold extreme dampness, Intake of harmful food stuffs like excessive curd consumption after eating fruits, vegetables and tubers produce toxic factors which affects muscles and bones produce Vatha diseases.

"என்னவே வாதந்தா னெண்பதாகும்
இகத்திலே மனிதர்களுக் கெய்யுமாறு
பின்னவே பெண்தனையே சோரஞ்செய்து
பெரியோர்கள் பிராமணரைத் தூடணித்தும்
வன்ன தேவச் சொத்தில் சோரஞ் செய்து
மாதா பிதா குருவை மறந்த பேர்க்கும்
கன்னவே வேதத்தை நிந்தை செய்தால்
காயத்திற் கலந்துடுமே வாதந்தானே"

- யூகி வைத்திய சிந்தாமணி-800
(பாடல் எண்.243, பக்கம் எண்.76)

Breach of trust, abusing the pious, elderly people, priests and holy spirits, exploitation of charitable properties, ingratitude towards mother, father and teacher results in Vatha diseases.

"தானென்ற கசப்போடு துவர்ப்பு கைப்பு
சாதகமாய் மிஞ்சுகினும் சமைத்த வண்ணம்
ஆனென்ற ஆறினது புசித்த லாலும்
ஆகாயத் தேறலது குடித்தலாலும்
பானென்ற பகலுறக்க மிராவிழிப்பு
பட்டினியே மிகவுறுதல் பாரமெய்தல்
தேனென்ற மொழியார் மேற்சிந்தை யாதல்
சீக்கிரமாய் வாதமது செனிக்குந்தானே"

- யூகி வைத்திய சிந்தாமணி-800
(பாடல் எண்.244, பக்கம் எண்.76)

Excessive intake of bitter, astringent and salty foods, intake of dry and old cooked rice, drinking polluted rain water, irregular sleep patterns, undue starving, excessive weight lifting and sexual perversion can induce Vatha diseases.

"ஆனான வறன் றன்னையே மதியா மாந்தர்
அகதி பரதேசியர் கட் கன்ன மீயார்
கோனான குருமொழியை மறந்தபேர்கள்
கொலைகளவு பொய்மங் குறித்த பேர்க்கு
உளனான சடந்தன்னில் வாதம் வந்து
உடற்பவிக்கும் வேதத்தி லுண்மை தானே"

- யூகி வைத்திய சிந்தாமணி-800
(பாடல் எண்.253, பக்கம் எண்.95)

Disobedience attitude towards God, refusing food for destitute and Sanyasi, disagreeing the advice of preceptors, stealing, unjustice and speaking lie leads to Vatha diseases.

4). According to Theraiyar in **Theraiyar Vagadam** text,

"வெய்யிலில் நடக்கையாலும் மிகத் தண்ணீர் குடிக்கையாலும்
சேய்யிழை மகளிரைச் சேர்ந்தன பலிக்கையாலும்
பையனே உண்மையாலும் பாகற்காய் தின்கையாலும்
தையலே வாதரோகம் சனிக்கு மென்றறிந்து கொள்ள"

- தேரையர் வாகடம்
(பாடல் எண்.16, பக்கம் எண்.5)

Excessive exposure in sunrays, excessive intake of water, excessive sexual activity, intake of bitter guard may disturb the normal functions of Vatham.

5). According to **Pararasa Sagaram,**

"தொழில்பெறு கைப்புக் கார்த்தல் துவர்த்தல் விஞ்சுகினுஞ் சோறும்
பழையதாம் வரகு மற்றைப் பைந்திணை யருந்தி னாலும்
எழில்பெறப் பகலு றங்கி இரவினி லறங்கா தாலும்
மழைநிகர் குழல னாளே வாதங்கோ பிக்குங் காணே"

Improper dietary habits and sleep pattern can cause Vatha diseases.

"காலங்கண் மாறி யுண்ணுங் காரியத் தாலுந் தண்ணீர்
சாலவே யருந்தி னாலுஞ் சந்தியி லுட்கார்ந்தாலும்
வாலவார் முலைநல் லாளே வாதமுற் பவிக்குங்காயே"

- பரராச சேகரம்

Irregular food habits, intake of excessive water, sitting in the cold air at evening hours leads to Vatha diseases.

"பாரினிற் பயப்பட்டாலும் பலருடன் கோபித்தாலும்
காரெனக் கருகியோடிக் கழுமரத்து ரத்தினாலும்
ஏர்பெறு தனது நெஞ்சின் மிகத்துக்க மடைந்திட்டாலும்
பாரிய காற்றினாலும் படரீனும் வாதங்காணும்"

- பரராச சேகரம்

Fear, angry, anxiety, stress, exposure to cool air can cause Vatha diseases.

6). According to Agasthiyar in **Agasthiyar Gunavagadam,**

"விவரமடா அசதி சன்னி மூளை நோவு
விரிவான மூளையது மிருதுவாகி
அவனிதனில் திடமாகப் போவதாலும்
அப்பனே மூத்திர குண்டிக்காய் வியாதியாலும்
தவமுனிவர் தீர்க்காக்கை மேக ரோகம்
தன்மையுள்ள முத்தண்டு கொடிவியாதி
அவமிலாப் பரிச நரம்பழுத்தங் கண்டால்
அணுகுமடா வாதநோய் ஆகும்பாரே"

- அகத்தியர் குணவாகடம்

Fatigue, Epilepsy, Brain diseases, Renal diseases, Genito urinary diseases, Connective tissue disorders induced Vatha diseases.

c). Factors of Kanmam (Hereditary):

In Siddha system many diseases are said to be caused by Kanmam which means the deeds committed by an individual in his / her present and previous births.

According to **Agasthiyar Kanma Kandam-300**,
"நூலென்ற வாதம் வந்த வகைதானேது
துண்மையாய்க் கன்மத்தின் வகையைக் கேளு
காலிலே தோன்றியது கடுப்பதேது
கைகாலில் முழக்கியது வீக்கமது
கோலிலே படுகின்ற விருட்சமான
குழந்தை மரந்தனை வெட்டல் மேல்தோல்சீவல்

நூலிலே சீவஜந்து கால் முறித்தல்
நல்லகொம்பு தழைமுறித்தல் நலித்தல் தானே"

- அகத்தியர் கன்மகாண்டம்
(பாடல் எண்.56, பக்கம் எண்.23)

Vatha Kanma Varalaru says that the psychological factors such as removing the bark of living trees, injuring the animals, cutting the branches in the living trees and plucking the leaves may produce Vatha diseases.

CLINICAL FEATURES:

"வழுத்தவே மூலாதாரத்தைப் பற்றியே
மருவியே மேலேறி முதுகுண்டாதல்
விழுத்தவே சிரசில் வந்து வியர்வுமாகி
விகுவாக நோவாகி மேனி கன்னி
பழுத்தவே உடம்பெங்கும் பஞ்சு போலாம்
பாங்கான மலசல மஞ்சளாகும்
குழுத்தவே தெண்டமாம் வாதந்தன்னைக்
கூறினோங் குணமெல்லாங் கூர்ந்து பாரே
கூர்ந்திட்ட மலசலங்கள் துரிதமானால்
கொண்டடக்கிப் பின்புதான் கொடிதாய் தள்ளி
ஊர்ந்திட்ட சரீரத்தி லுதிர மீறி
உறத்தேய்த்துத் தலையதனி லெண்ணெய் வார்க்கில்
வார்த்திட்ட வழி நடக்கில் மெத்த வந்தான்
வாதந் தானுற்பவித்து நடை கொடாமல்
நார்ந்திட்ட நரம்போடு எலும்பிற் சூழ்ந்து
நணுகியே யோடி நெஞ்சி வேறுந் தானே"

- யூகி வைத்திய சிந்தாமணி-800
(பாடல் எண்.288,289 பக்கம் எண்.109,110)

Review of Literature described below says the pain in low back area with the clinical features more or less correlates with the Thandaga Vatham.

i). **According to Dhanvanthri Vaidhyam,**

"ஆமகட்டதனால் வாயு வதிகமாய்ச் சிலேற்பனத்தைத்
தாமகட்டாகச் சேர்த்துத் தடித்திடுஞ் சரீரமெல்லாம்
நோமக் கட்டான மேனி நுவலிளைப் பெயர்ப்புத் தோன்றும்
தாமக் கட்டான ரோகந் தண்டக வாதமாமே"

- தன்வந்திரி வைத்தியம்

Vatham is associated with Kapham results in generalised odema, obesity and generalised debility in Thandaga Vatham.

ii). **According to Roganiga nirnayasaram:**

"தேகம் தண்டத்தை போல் விழுந்து அசைவில்லாமல் இருக்கும்"

Body is rendered like a log of wood.

iii). **According to Jeevaratchamirtham,**

வாயுவானது எண்ணெய் வஸ்து, மந்த வஸ்து, சீத வீரிய வஸ்து, தயிர், அதிக லவணம், பகல் நித்திரை, பதினான்கு வேகங்களை மறித்தல் ஆகிய இவைகளினால் பிறந்த சப்த தாதுக்களிலும் வியாபித்து அவைகளைக் கலைத்து விட்டு ஆமாசயஸ்தானத்தை அனுசரித்துச் சிலேஷ் பித்தங்களைத் தன்னுடன் சேர்த்துக் கொண்டு அவயங்களின் செயலை மாற்றி விடும். இதனால் ரசாதி தாதுக்களில் மரத்தல் (Numbness), சீதளம் (Cold), உள்ளெரிச்சல் (Burning Sensation), சரீரங் கனத்தல் (Heaviness of body), ஞாபக மறதி (Loss of Memory), பிரமை (Psychosis),அதிக வேதனை (Severe pain), நீர்க்கட்டு (Anuria) என்னும் இக்குறிகுணங்களோடு தேகமானது தண்டத்தைப் போல விழுந்து அசைதலும், நீட்டலும் மடக்கலும், எழுதலும் இல்லாதிருக்கும் (Body is rendered like a log wood and unable to flex, extend and rotate).

- அனுபோக வைத்திய தேவரகசியம்
(முதல் பாகம், பக்கம் எண்.164).

iii). **According to Sikitcharatna Deepam:**

வாயுவானது மூலாதாரத்தைப் பற்றி மேலேறி முதுகிலிருந்து சிரசில் வந்து வியர்த்து நோயுண்டாக்கி சர்வாங்கத்தையும் நோயுறச் செய்வதுடன் மலசலம் மஞ்சள் வர்ணமாகவும், தேகத்தை தண்டகம் போல் நீட்ட விடாமல் செய்யும்.

- Excessive sweating all over the body
- Yellow coloured urine
- Body is found to be like a log of wood

"இடுப்பது கடுத்து உளைந்து
இடைவிடா வலித்துக் கொள்ளும்
முடுக்கமாய் குனியவே தான்
முடுகியே நிமிர வொட்டாது
துடுக்கென வந்து அடரும்
சுரமது அற்பம் அற்பம்
சுடக்கென இடுப்பைச் சுற்றி
சார்ந்திடும் வாதம் தானே....."

- வாதநோய் மருத்துவம்
(பக்கம் எண்.114)

Here in **Idupu Vatham,** pain aggrevates while walking and subsides at rest; While lying on bed, the patient is unable to move their lower back.

மேலும்,

"நடப்பென போது மெத்த நய்யவே வலிக்குமென்ன
கெடப்பெனபோதும் சற்றே குணமென தோன்றுமாகில்
படுப்பன போதும் யாமம் பாகியால் வாதமுண்டாம்
இடுப்பென சேரும் வாதத்தியலிது எண்ணுவீரே"

- வாதநோய் மருத்துவம்
(பக்கம் எண்.114)

மேலும்,

Thandu Vatham, is described in **Vatha Noi Maruthuvam** has the clinical features given below:

Due to cold food stuffs, day time sleep, in case of Thandu Vatham the patient develops increase level of Vatham their by deranging the Pitham and Kapham. This leads to burning sensation **(உள் எரிச்சல்)**, psychosis **(பிரமை)**, asthma **(இளைப்பு)**and severe pain **(வேதனை).**

In **Thandu Vatham,** the low back bone gets inflammed resulting in generalised debility, pain, body becomes weaker.

"தண்டு வாதத்தின் குணத்தை சாற்றக்கோளாய் மடமாயிலே
பண்டேதண்டு மிக ஊதி பற்றிபொதுமி கொண்டிருக்கும்
விண்டோம் சில போதுளைவுண்டாம் மிகுந்த வாட்டமுண்டாம்
கொண்டே மனமும் தளர்ச்சியும் கோப மதிகம்காணுமென்றே"

- வாதநோய் மருத்துவம்
(பக்கம் எண்.126)

Due to the changes in Uyir thathus especially Vatham, the 96 Thathuvangal gets affected. As said above, due to various causes the following changes occurs in Thandaga Vatham.

DIAGNOSIS IN SIDDHA:

A). **Piniyari Muraigal** (Methods of Diagnosis) is based upon three main topic namely,

- ❖ Poriyal Aridhal (Physical Examination, Perception)
- ❖ Pulanal Aridhal (Palpation)
- ❖ Vinavudhal (Interrogation)

i). Poriyal Aridhal (Inspection):

'Poriyal Aridhal' means examining the five sense organs of perception.

ஞானேந்திரியங்களின் ஆய்வு		
புலன்கள்	**தொழில்கள்**	**தண்டக வாதத்தில் பாதிப்பு**
செவி	ஒலியை அறிய செய்ய	இயல்பு
மெய்	உடலில் ஊற்றை அறிதல்	முதுகில் வலி, வீக்கம்
கண்	ஒளியை அறியச் செய்தல்	இயல்பு
நாக்கு	சுவையை அறியச் செய்தல்	இயல்பு
மூக்கு	வாசனையை நுகரச் செய்தல்	இயல்பு

கன்மேந்திரியங்களில் ஆய்வு		
புலன்கள்	**தொழில்கள்**	**தண்டக வாதத்தில் பாதிப்பு**
வாய்	பேசச் செய்யும்	இயல்பு
கை	இடுதலும், ஏற்றலும் செய்யும்	இயல்பு
கால்	நடக்கச் செய்யும்	கால்களில் வலி நடக்கச் சிரமம்
எருவாய்	மலத்தைக் கழிக்கும்	மலச்சிக்கல்
கருவாய்	கரு, சுக்கிலத்தைக் கழிக்கும்	இயல்பு

ii). Pulanal Aridhal (Palpation):

By examining the pulan i.e., the sense organ of the patient, the physician can able to diagnose the disease.

iii). Vinavudhal (Interrogation):

Vinadhal is questioning and gathering information regarding the previous history of disease and clinical features which are much essential for diagnosis.

B). Envagai Thervugal (Eight Diagnostic Tools):

The excellent and unique diagnostic methods in the Siddha system is the Envagai Thervugal.

"நாடி ஸ்பரிசம் நா நிறம் மொழி விழி
மலம் மூத்திரமிவை மருத்துவராயுதம்"

- நோய் நாடல் நோய் முதல் நாடல்
முதல் பாகம் (பக்கம் எண்.270)

1. Naadi (Pulse):

Among the Envagai Thervugal,Naadi is most important. Naadi is felt as Vatham, Pitham and Kapham with the tip of the index, middle and ring fingers respectively over the lower end of the radius in right side for males and left side for females.

Normally Vatham, Pitham and Kapham are held in the ratio of 1:1/2:1/4. Derangement in this will reflect as disease. Naadi Nadai in Thandaga Vatham,

"திருத்தமாம் வாதத் தோடே தீங்கொடு பித்தஞ் சேரில்
பொருத்து கள்தோறும் நொந்து போதவே பிடிக்கும் சூலை"

- நோயின் சாரம் - சித்தமருத்துவம் (பொது)
(பக்கம் எண்.634)

"காணப்பா வாத மீறில்
கால்கைகள் பொருத்து நோகும்"

- காவியநாடி - சித்த மருத்துவம் (பொது)
(பக்கம் எண்.634)

"சொல்லிய வையத்தோடு பித்தமுங் கூடிற்றானால்
வல்லியம் போலக் குத்தும் மைந்தனே எலும்பு தோறும்"

- காவியநாடி - சித்த மருத்துவம் (பொது)
(பக்கம் எண்.634)

"அறிந்துபார் வாதமே தனித்தானதால்
சரிந்திடவே கால் முடக்கும்"

- அகத்தியர் ரத்தினச் சுருக்கம்
(பக்கம் எண்.634)

"வாதத்தில் சேத்துமமாகில் வலியோடு வீக்கமுண்டாம்"

- அகத்தியர் நாடி

In Thandaga Vatham the following Naadi Nadai are commonly felt.

- Vatham
- Vatha Pitham
- Pitha Vatham

In Thandaga Vatham,

2. Sparisam (Sensation to touch):

Heat, swelling, pain is found in some cases.

3. Naa (Tongue):

No abnormality is seen in Naa.

4. Niram (Colour):

Some skin colour changes seen in affected area due to inflammatory mechanism.

5. Mozhi (Voice):

No abnormality is seen.

6. Vizhi (Eyes):

Eye pallor is reported in some cases.

7. Malam (Faeces):

Constipation is reported in some cases.

8. Moothiram (Urine):

In urine, Neerkuri and Neikuri examinations are done.

Neikuri (Oil Examination):

Prior to the day of urine examination, the patient is instructed to take a balanced diet and quantities of food must be proportionate to his / her appetite. The patient should have no disturbed sleep. After waking up in the morning, the first voided urine is collected in a clear wide mouthed glass dish or china clay bowl and is subjected to analysis of 'Neerkuri' and 'Neikuri' within one and a half an hour of its collection.

The collected urine specimen is kept in a glass dish or china clay container and observed under direct sunlight without shaking the vessel. Then add one drop of gingelly oil and observed the spreading pattern and conclude as follows:

"அரவென நீண்டின ஃதே வாதம்
ஆழிபோற் பரவின் அஃதே பித்தம்
முத்தொத்து நிற்கின் மொழிவ தென் கபமே"

- நோய் நாடல் பாகம்-1
(பக்கம் எண்.298, 299)

Neerkuri:

"வந்த நீர்க்கரி யெடை மணம் நுரை எஞ்சலென்
றைந்தியலுளவை யறைகுது முறையே"

- சித்த மருத்துவாங்க சுருக்கம்
(பக்கம் எண்.510)

In urine examination the following characteristic features are observed namely.

Niram	-	Colour
Edai	-	Specific gravity
Manam	-	Smell
Nurai	-	Frothy nature
Enjal	-	Quality of urine voided

Apart from these, frequency of micturition, abnormal constituents such as sugar, protein, blood stains, pus, crystals also to be found out.

C). Paruvakaalam (Seasonal variations):

Sl. No.	State of Kuttram	Kaalam
1.	Vatham thannilai adaithal	Munpani Kaalam, Pinpani Kaalam, Koothirkaalam, Elavenil Kaalam
2.	Vatham thannilai valarchi	Muthuvenil Kaalam
3.	Vatham vetrunilai valarchi	Karkaalam

முதுவேனிற் காலத்தில் நமது உடலில் வறட்சி ஏற்பட்டு வளிநோய் வருவதற்கு ஏதுவாகிறது.

D). திணை (Geographical distribution):

குறிஞ்சி : மலையும், மலை சார்ந்த பகுதியும்
முல்லை : காடும், காடு சார்ந்த பகுதியும்
மருதம் : வயலும், வயல் சார்ந்த பகுதியும்
நெய்தல் : கடலும், கடல் சார்ந்த பகுதியும்
பாலை : மணலும், மணல் சார்ந்த பகுதியும்

முல்லை மற்றும் நெய்தல் நிலங்களில் வாத நோய்கள் பெருமளவில் ஏற்படும்.

E). ஏழு உடல் தாதுக்களின் ஆய்வு (Seven Udal thathukkal Examination):

Sl. No.	Udal Thathukkal	Normal Functions	Increased conditions	Decreased conditions
1.	Saaram	Strengthens the body and mind.	Loss of appetite, excessive salivation.	Tiredness, fatigue, diminished activity of the sense organs.
2.	Senneer	Preserves brightness, boldness, power and knowledge.	Boils and tumours in different parts of the body, spleenomegaly, colic pain, increased blood pressure, red eyes and skin, Jaundice, leprosy, Haematuria.	Tiredness, Lassitude, Anemia.
3.	Oon	Gives structure and shape to body, Represents the tissues.	Tumours or extra growth around the neck, face, abdomen, thigh, genitalia etc., with dyspnoea.	Muscle wasting
4.	Kozhuppu	Lubricate the joints.	Tumours or extra growth around the neck, face abdomen, thigh, genitalia etc., with dyspnoea and loss of activity.	Pain
5.	Enbu	Physical bone structure.	Extra growth of bone and teeth	Weak bones, teeth, nails and hair.
6.	Moolai	It is present in the bones and gives strength to them.	Heaviness, swollen eyes, swollen phalanges, oliguria and non-healing ulcers.	Osteoporotic changes.
7.	Sukkilam or Suronitham	Meant for reproduction and inheritances.	Increased sexual activity and symptoms as that of urinary calculi.	Infertility, pain in genitalia.

In Thandaga Vatham:

Saaram, Seener, Kozhuppu, Enbu thathukkal are commonly affected.

Saaram : Weakness, tiredness of body.

Seener : Early morning stiffness occurs in affected joints.

Kozhuppu : Restricted movements in joints and reduced Inter vertebral disc.

Enbu : Produces degeneration in lumbar vertebrae, spondylotic changes and extra osteophytic formation

F). முக்குற்றங்களின் ஆய்வு (Mukkutram examination):

Sl. No.	Vatham	Location	Function	In Thandaga Vatham
1.	Pranam	Chest region	Regulate respiration and controls the mental functions, functions of heart, lungs and brain	Not Affected
2.	Abanam	Pelvic region	Control excretion such as sweating evacuation of stools, ejaculation of sperms, micturition, menstruation and parturition.	May be Affected
3.	Viyanan	Nose and skull	Helps in various movements of the body and responsible for nervous functions and sensation	Affected
4.	Uthanan	Thorat	Responsible for speech, vomiting, hiccough, cough.	Not affected
5.	Samanan	Navel	Regulates the digestion and controls all the other vayus.	Affected
6.	Nagan	Eyes	Helps in opening and closing of the eyes, intelligence.	Not affected
7.	Koorman	Eye	Responsible for vision, closure of eyelids.	Not affected
8.	Kirukaran	Saliva	Secretion of saliva and mucous secretion in nasal cavity, helps concentration.	May be affected
9.	Devathathan	Ocular muscles	It is responsible for laziness and eyeball movements	May be affected
10.	Thananjeyan	-	It is responsible for degradation of body after death	-

Pitham:

Sl. No.	Pitham	Functions	In Thandaga Vatham
1.	Analagam	Digestion	May beaffected
2.	Ranjagam	Gives colour to blood	May be affected
3.	Sathagam	Responsible for wilful activities	Affected
4.	Prasagam	Gives luster to skin	Not affected
5.	Alosagam	Gives strength to eyes	Not affected

Kapham:

Sl. No.	Kapham	Functions	In Thandaga Vatham
1.	Avalambagam	Respiratory function	Not affected
2.	Klethagam	It lubricates the food	May be affected
3.	Pothagam	Responsible for taste sensation	Not affected
4.	Tharpagam	It acts as coolent for eyes	Not affected
5.	Santhigam	It maintains the integrity of joints	Affected

DIFFERENTIAL DIAGNOSIS:

Thandaga Vatham is different from the following diseases,

1. **ஆசுவதம்ப வாதம்:**

"வாதமா யுடல்வெளுத்து வழவெல் லாநேரம்
மயக்கமோ டிருமலா யூளை யுண்டாம்
நேதமாய் நெஞ்சடைத்தப் பொறி கலங்கும்
நெருப்பாக உடல்காணு நெடுமூச்சுண்டாம்
கோதுதான் மயக்கத்தில் மருந்தி நீட்டால்
குளிர்ச்சியாய்க் கோபிக்குங் கூச்சலுண்டாம்
பாதந்தான் திமிருண்டாய் முட்போலாகும்
படுத்த ஆசுவதம்பம் பகரலாமே"

- யூகி வைத்திய சிந்தாமணி-800
(பாடல் எண்.284, பக்கம் எண்.108)

The clinical features are:

1. Paleness of the body
2. Cough
3. Heaviness of chest
4. Numbness of both lower limbs
5. Pain present in vertebral column

2. ஊருத்தம்ப வாதம்:

"ஆமென்ற வாதமது உள்ள டங்கி
ஆடித்துடைதான் குறங்கிரண்டு மளவாய்ப் பற்றி
காமெனற் கைகாலில் விரலு சுற்றிக்
கனத்துமே சாணியது பொதிந்தார் போலத்
தேமென்ற சிரந்தனிலே பார முண்டாய்த்
தேமெங்கு மூதியே திமிருண்டாகும்
நாமென்ற நடக்கொணர வொடுக்க மாகி
நலியூருந் தம்பமது நனுகுங்கானே"

- யூகி வைத்திய சிந்தாமணி-800
(பாடல் எண்.260, பக்கம் எண்.98)

The clinical features are,

1. Heaviness in both thighs.
2. Feelings of cow dung applied over fingers of both hands and feet.
3. Whole body perceives numbness.
4. Difficulty in walking.

3. வாதஸ்தம்பம்:

"உற்பவிக்கும் வாதமது எழுந்து பொங்கி
உயர்காலின் புறவடியைக் குடைந்து பற்றி
தெற்பவிக்கும் வீக்கமாய்ச் செழும்ப லுண்டாய்த்
தேகமெங்கும் நோவாகித் திமிரு மாகி
விற்புவிக்கும் வில்லுபோல விதனமாகி
மிடுக்கான மாந்தனைப் போல் விதனமாகி
பற்பவிக்கும் பரன்றனையே நினையாமூர்
படுகின்ற வாதஸ்தம் பமுமாம் பாரே"

- யூகி வைத்திய சிந்தாமணி-800
(பாடல் எண்.254, பக்கம் எண்.96)

The clinical features are,

1. Dorsum of the feet gets affected, they look shining with odema, intense pain.
2. Whole body appears to be weak and fatigue.
3. Body is bend like a bow.
4. Makes a strong built man to bend and bow while walking.

In Thandaga Vatham, diffuse low back pain, stiffness, radiating pain to lower limbs, yellow coloured stools and urine are present.

b). MODERN ASPECTS

Lumbar Spondylosis is a form of lower back pain and is an important clinical, social, economic and public health problem affecting the worldwide population. It is a disorder with many possible etiologies and many definitions.

DEFINITION:

Lumbar spondylosis, also known as lumbar osteoarthritis can be described as all degenerative conditions affecting the discs, vertebral bodies, and associated joints of the lumbar vertebrae. Spondylosis of lumbar region is considered as the hypertrophic response of adjacent vertebral bone to disc degeneration (although osteophytes may infrequently form in the absence of diseased discs)

TACKLING THE TERMINOLOGY:

The terms lumbar osteoarthritis, disk degeneration, degenerative disk disease, and spondylosis are used in the literature to describe anatomical changes to the vertebral bodies and intervertebral disc spaces that may be associated with clinical pain syndromes. Within the literature, lumbar spondylosis encompasses numerous associated pathologies including spinal stenosis, degenerative spondylolisthesis, osteoarthritis, spinal herniation.

EPIDEMIOLOGY:

Age:

The incidence of lumbar spondylosis is 27-37% of the asymptomatic lower back pain population. Worldwide, more than 80% of individuals older than 40 years have lumbar spondylosis, increasing from 3% of individuals aged 20-29 years. Approximately 84% of men and 74% of women have vertebral osteophytes, most frequently at T9-10 and L3 levels. Approximately 30% of men and 28% of women aged 55-64 years have lumbar osteophytes. Approximately 20% of men and 22% of women aged 45-64 years have lumbar osteophytes.

Sex:

Sex ratio reports have been variable but are essentially equal. Gender seems to be distinctly in the form of lumbar spondylosis, and disc space narrowing with or without osteophytes in women may be a risk factor for low back pain.

CAUSES AND RISK FACTORS:

There are primary and secondary causes

a) Primary causes:

- **The role of heredity:**
    - Genetic factors likely influence the formation of osteophytes and disc degeneration. 50% of the variability found in osteoarthritis can be attributed to heriditary factors. Similarly, twin studies evaluating the progression of degenerative changes in lumbar MRI imaging suggest that approximately half (47-66%) of the variance could be explained by genetic and environmental factors, attributing only 2-10% of variance to physical loading and resistance training. Another twin study revealed a high degree of similarity in signal intensity, disk height narrowing, disk bulging, and end-plate changes. A search for these underlying genetic factors has identified polymorphisms in genes regulating inflammatory pathways and a Vitamin D Receptor allele to correspond to radiographic progression of lumbar disc degeneration.

- Spinal osteophytosis in post menopausal Japanese women correlated with the CC genotype of the transforming growth factor β_1 gene.
- Congenital narrowing of the spinal canal (myelopathty is often seen when canal's sagital diameter is 12mm or less).
- Segmental defects-Hemi vertebra, Fused Vertebra.

❖ **Metabolic Factors:**

- **Adiposity** is seen as a major risk factor. The spine is designed to carry the body's weight and distribute the loads encountered during rest and activity. When excess weight is carried, the spine is forced to assimilate the burden, which may lead to structural compromise and damage. One region of the spine that is most vulnerable to the effects of obesity is the low back-the lumbar spine.
- **Smoking** - Bone is a living tissue dependent on the functions and support provided by the other body systems. When these systems are not able to perform normally, bone is unable to rebuild itself. The formation of bone is particularly influenced by physical exercise and hormonal activity, both of which are adversely affected by cigarette smoking.Many smokers have less physical endurance than non-smokers, mainly due to decreased lung function. Cigarette smoking reduces the amount of oxygen in the blood and increases the level of harmful substances, such as carbon mono oxide. This combined with the effects of smoking on the heart and blood vessels, can limit the benefits from physical activity.In men and women, cigarette smoking is known to influence hormone function. Smoking increases estrogen loss in women who are perimenopausal orpostmenopausal. This can result in a loss of bone density and spinal diseases.
- **Alcoholism**-Lack of Muscular Support: because alcohol is a natural muscle relaxant, consumption can decrease support in the back, buttocks, pelvic, and abdomen regions of your body, making the body and spine work harder to stay upright.

Poor Blood Flow: Blood circulation is one of the affected process of drinking,and a lack of proper circulation can lead to muscle, and organ damage, as well causing nerves in the spinal column to become irritated due to lack of oxygen andblood flow.

- **High triglycerides level**- High blood cholesterol and triglycerides serum levels are risk factors for atherosclerosis, which could be responsible for a decreased in the blood supply to the already poor vascularized IVD (Inter Veretebral Disc]. At tissue level, structures with precarious nutrient supply, such as the IVD, may suffer and gradually degenerate as a consequence of failure of nutrient supply to IVD cells
- **High blood pressure**
- **High blood glucose level**-Diabetes is a multi organ disease that affects many types of connective tissues, including bone and cartilage.It causes the ossification of the posterior longitudinal ligaments and bone, which leads to spinal stenosis and nerve pressure.

❖ **The influence of age:**

- The aging process to be the strongest risk factor for bony degeneration, particularly within the spine.It is found increasing age to be significantly associated with osteophyte formation but not predictive of the degree of disc space narrowing.

❖ **The impact of activity and occupation:**

- Disc generation has long been associated with certain activities. Retrospective of Body Mass Index (BMI), incident back trauma, daily spineloading (twisting, lifting, bending, and sustained non-neutral postures), and whole bodyvibration (such as vehicular driving) to be factors which increase both the likelihood and severity of spondylosis.

❖ **Vicious attitude**

b) Secondary causes:

- Osteo arthritis
- Rheumatoid arthritis
- Metastatic carcinoma
- Lymphoma of Spine
- TB Spine
- Road accidents
- Accidental Injury
- Old Lumbar Fracture
- Past spine surgery
- Acquired narrowing of lumbar spinal canal dueto

    - **Osteophytes:** Osteophyte formation may represent a remodeling process, functionally adapting to the instability or the changes in the demands of the spine. Likewise, it emphasizes the dynamic and reparative qualities of the intervertebral disc, responding to variations in mechanical loading and influencing vertebral kinematics. Osteophytes may form in the absence of other degenerative processes, and cartilaginous damage may exist without corresponding osteophytes. Although there remains a strong association between the presence of osteophytes and other degenerative spine changes, isolated instances of one without the other occur, in the absence of overt symptoms.
    - Sacralisation of L5 vertebrae
    - Ossified Posterior Longitudinal Ligament(OPLL)
    - Facet joint hypertrophy(results foraminal stenosis&compression of root of radiculo arthropathy)
    - Hypertrophied ligamentum flavum(Compress the cord during extension)

PATHOPHYSIOLOGY:

The high incidence of simultaneous degenerative changes to the intervertebral disc, vertebral body, and associated joints suggests a progressive and dynamic mechanism, with interdependent changes occurring secondary to disc space narrowing.

Intervertebral Joints:

Adjoining vertebrae are connected to each other at three joints. There is a median joint between the vertebral bodies and two joints right and left between the articular processes.

The joints between the articular processes are plane synovial joints.

The joint between the vertebral bodies is a symphysis. The surfaces of the vertebral bodies are lined by thin layers of hyaline cartilage. Between these layers of hyaline cartilage there is a thick plate of fibrocartilage which is called the intervertebral disc.

Intervertebral Discs:

These are fibrocartilaginous discs which intervene between the bodies of adjacent vertebrae and bind them together. Their shape corresponds to that of the vertebral bodies between which they are placed. The thickness of the disc varies in different regions of the vertebral column, and in different parts of the same disc. In the cervical and lumbar regions the discs are thicker in front than behind, while in the thoracic region they are of uniform thickness. The discs are thinnest in the upper thoracic region and thickest in the lumbar region.

The discs contribute about one-fifth of the length of the vertebral column. The contribution is greater in the cervical and lumbar regions than in the thoracic region.

Each disc is made up of the following two parts:

1. Nucleus Pulposus is the central part of the disc. It is soft and gelatinous at birth. It is kept under tension and acts as a hydraulic shock absorber. With advancing age the elasticity of the disc is much reduced.

2. Annulus Fibrosus forms the peripheral part of the disc. It is made up of a narrower outer zone of collagenous fibres and a wider inner zone of fibrocartilage. The fibres from laminae that are arranged in the form of incomplete rings. The rings are connected by strong fibrous bands. The outer collagenous fibres blend with the anterior and posterior longitudinal ligaments.

Intervesrtebral discs are believed to undergo a "degenerative cascade" of three overlapping phases that may occur over the course of decades.

Phase-I (Dysfunction Phase): 15to 45 yearsdescribes the initial effects of repetitive micro trauma with the development of circumferential painful tears of the outer, innervated annulus, and associated end-plate separation that may compromise disk nutritional supply and waste removal. Such tears may coalesce to become radial tears, more prone to protrusion, and impact the disc's capacity to maintain water, resulting in desiccation and reduced disk height. Fissures may become ingrown by vascular tissue and nerve endings, increasing innervation and the disc's capacity for pain signal transmission.

Phase-II (Instability Phase): 35 to70 yearsis characterized by the loss of mechanical integrity, with progressive disc changes of resorption, internal disruption, and additional annular tears, combined with further facet degeneration that may induce subluxation and instability.

Phase-III (Stabilization Phase): 60 years and above is continued disc space narrowing and fibrosis occurs along with the formation of osteophytes and transdiscal bridging.

There is a spectrum of pathological changes in facial joints and the disc and the interaction of these changes. Adjacent pedicles approximate with a narrowing of the superior-inferior dimension of the intervertebral canal. Laxity due to modestredundancy of the longitudinal ligaments enables bulging of the ligamentum flavum and potential for spine instability. Increased spine movement permits subluxation of the Superior Articular Process (SAP), causing a narrowed anteroposterior dimension of the intervertebral and upper nerve root canals. Laxity may also translate into altered weight mechanisms and pressure relationships on

vertebral bone and joint spaces believed to influence osteophyte formation and facet hypertrophy to both inferior and superior articular processes with risks for projection into the intervertebral canal and central canal, respectively. Oblique orientations of the articular processes may further cause retrospondylolisthesis, with resulting anterior encroachment of the spinal canal, nerve root canal, and intervertebral canal.

Biochemical research exploring osteophyte formation supports the above process. Osteophyte lipping is believed to form at periosteum through the proliferation of peripheral articular cartilage which subsequently undergoes endochondral calcification and ossification. Changing weight mechanics and pressure forces as well as alterations in oxygen tension and dynamic fluid pressure appear to be influential factors in osteophyte formation. Mesenchymal stem cells of the synovium or periostium are likely precursors, with synovial macrophages and a milieu of growth factors and extracellular matrix molecules acting as probable mediators in this process.

SIGNS AND SYMPTOMS:

When a patient suffers from lumbar spondylosis, it is possible that osteophytes are formed. These osteophytes are bony overgrowths that occur due to the stripping of the periost from the vertebral body.

- Pain- can be produced when a neural foraminal stenosis is formed, which comes from the formation of osteophytes.
- Joint stiffness, which can limit motion.
- Neurologic claudication, which includes:
    - Lower back pain,
    - Leg pain,
    - Numbness when standing and walking.
- Radiating pain towards the lower extremities
- Diffuse tenderness in lumbar bone
- Exacerbation of pain on movements
- Pain increased on forward bending, sneezing, coughing
- Paraesthesia and sensory loss on affected area
- Burning and tingling sensation in lower limb
- Pain and stiffness in low back in the morning hours

Less Common Symptoms:

- ❖ Loss of balance
- ❖ Neurogenic bladder.

EXAMINATION:

When a physician performs an examination for lumbar spondylosis, it is advised to follow the principles of the general spine examination and apply them to this specific pathology. General examination of the spine:

- The examination should begin with careful observation during the whole consultation.
- It is essential to observe the patient's gait and posture.

1. Inspection:

- Inspection of the entire spine.
- Look for any obvious swellings or surgical scars.
- Assess for deformity: scoliosis, kyphosis, loss of lumbar lordosis orhyperlordosis of the lumbar spine. Look for shoulder asymmetry andpelvic tilt.

2. Palpation:

- Palpate for tenderness over bone and soft tissues.
- Perform an abdominal examination to identify any masses and consider a rectal examination to exclude other pathologies in this region

Inference:

- No tenderness to palpation is noted, but some discomfort can be elicited with deep percussion over the midline of the lumbar area.
- Physical findings that may also be present include antalgic or normal gait, tight lumbar musculature and hamstrings, hyperlordosis, and buttock or thigh pain.

3. Movement:

- Examination of the spine must also include examination of the shoulders and examination of the hipsto exclude these joints as a cause of the symptoms.

i) To test flexion:

Instruct the patient to bend forwards as much as possible at the waist. Normal flexion is 80^{o} or finger tips 3-4 inches from the floor.

ii) Lateral Flexion:

Instruct the patient to bend to the left and to the right as far as possible.Normal range is 35^{o}on each side.

iii) Extension:

Instructs the patient to bend at waist as far backward as possible. Normal range is 20^{o}-30^{o}.

iv) Rotation:

Instructs the patient to rotate from the waist to the left and to the right as far as possible. Normal range is 45^{o}C possible.Range of motion is full.

4.Neurovascular examination:

- A thorough examination of sensation, tone, power and reflexes should be performed.
- Always consider the possibility of acute spinal cord compression, which is a neurosurgical emergency.
- All peripheral pulses should also be checked, as vascular claudication in the upper and lower limbs can mimic symptoms of radiculopathy or canal stenosis

5. Tests for Examination:

- Straight Leg Raising test (SLR)
- Braggard's test
- Femoral nerve stretch test
- Schober's test
- Forward bending to touch the toes
- Flip test
- Lassegues test
- Bowstring sign

OUTCOME MEASURES:

Numeric Pain Rating Scale (NPRS): The patient is asked to score 3 pain rating, (worse/current/ best) over the last 24hour. The score for this scale is the average of these 3 values. This scale is a variant of the VAS but also assess pain intensity.

Roland Morris Disability Questionnaire (RMDQ): This questionnaire contains sentences that people have used to describe themselves when they have back pain on that specific day. As people read the list they might recognize themselves and then they must tick that box. A score is appointed according to the amount of boxes the patient fills in. This questionnaire makes it possible to follow changes in time.

Oswestry Disability Index (ODI): This index is made to evaluate how back pain invalidates people in their daily activities (sleeping, self-care, sex life, social life and travelling). Each question contains 6 categories (0: no limitation 6: most limitation). The score is calculated by the sum of the 10 questions, multiplied by 2. This value represents the percentage of invalidation.

PainSelf-Efficacy Questionnaire (PSEQ): This questionnaire rates how confident patients feel performing activities despite the pain. This is indicated on a scale from 0 (no confidence) to 6 (completely confident). All the scores are then added up to a score from 0 to 60. Where the closer to 60 means that the patients have a stronger self-efficacy belief. There are also short versions of this questionnaire available who shows also a great responsiveness.

Patient-Specific Functional Scale: Questionnaire where patients are asked to identify up to three activities that they had difficulty with or are unable to perform as a result of their back pain. Each item is given a score of 0-10 (unable- able). The total score is assessed by the sum of the activity scores/number of activities (Minimum detectable change (90%CI) for average score = 2 points, Minimum detectable change (90%CI) for single activity score = 3 points) of all those questionnaires the NRPS is recommended for assessing pain because of this ease of administration and responsiveness. The ODI and RMDQ are recommended for assessing functioning.

DIAGNOSTIC PROCEDURES:

For the clinical diagnosis of lumbar spondylosis, a thorough investigation is necessary to ensure that other pathologies are excluded.

- **MRI:** Shows the fine details of the spine and is used to visualize the intervertebral discs, including the degree of disc herniation, if present. An MRI is also used to visualize the vertebrae, the facet joints, the nerves, and the ligaments in the spine and can reliably diagnose a pinched nerve.

- **X-Rays:** show bone spurs on vertebral bodies in the spine, thickening of facet joints (the joints that connect the vertebrae to each other), and narrowing of the intervertebral disc spaces.

- **CT scan:** able to visualize the spine in greater detail and can diagnose narrowing of the spinal canal (spinal stenosis) when present.

- **SPECT:** Single-photon emission computed tomography.

- **Bone scintigraphy** is used to further evaluate patients with suspected spondylosis. Controversy surrounds the designation of one of these tests as most useful in the evaluation of spondylosis.

- **Myelogram:**

  Helping in detecting:

  - Intra spinal lesion
  - Spinal stenosis
  - Any compression of the spinal cord

- **Disco graphy**
- **Nerve conduction studies**
- **EMG**

These procedures were validated in several studies, which concluded that MRI was effective (92% sensitivity) in identifying pars lesions. CT scan was also used as a

diagnostic procedure, but the result weren't equally positive. That's the reason why MRI is advised as the best method of diagnosis.

DIFFERENTIAL DIAGNOSIS:

When a patient is suffering from low back pain, there are a lot of possible pathologies that could be the cause of this pain. Along with lumbar spondylosis, there are other causes as well:

Rheumatoid Arthritis:

Rheumatoid Arthritis (RA) is a long-term autoimmune disorder that primarily affects joints. It typically results in warm, swollen, and painful joints. Pain and stiffness often worsen following rest. Most commonly, the wrist and hands are involved, with the same joints typically involved on both sides of the body. The disease may also affect other parts of the body. This may result in a low red blood cell count, inflammation around the lungs, and inflammation around the heart. Fever and low energy may also be present.Often, symptoms come on gradually over weeks to month.

Bekhterev's Disease (Ankylosing Spondylitis):

Ankylosing Spondylitis (AS) is a type of arthritis in which there is long term inflammation of the joints of the spine Typically the joints where the spine joins the pelvis are also affected. Occasionally other joints such as the shoulders or hips are involved. Eye and bowel problems may also occur. Back pain is a characteristic symptom of AS, and it often comes and goes.Stiffness of the affected joints generally worsens over time.

Multiple myelomas

Also known as plasma cell myeloma, is a cancer of plasma cells, a type of white blood cell normally responsible for producing antibodies. Initially, often no symptoms are noticed. When advanced, bone pain of the affected region, bleeding, frequent infections, and anemia may occur

Multiple sclerosis is a long-lasting demyelinating disease in which the insulating covers of nerve cells in the brain and spinal cord are damaged, even the optic nerves

in eyes. It can cause problems with vision, balance, muscle control, and other basic body functions.

Extra dural tumor
Lumbar Degenerative Disk Disease
Lumbar Facet Arthropathy
Osteoporosis
TB Spine
SLE

COMPLICATIONS:

- Nerve compression from posterior osteophytes is a possible complication only if a neuroforamen is reduced to less than 30% of normal.
- If lumbar spondylosis projects into the spinal canal, spinal stenosis is a possible complication
- If osteophytes disappear, look for aortic aneurysm. Aortic aneurysms can cause pressure erosions of the adjacent vertebrae. If osteophytes are present, the first sign is often erosion of those osteophytes, so they are no longer visible.
- An isolated report of a bony L4 mass pressing on the duodenum has been described.
- Cauda equina syndrome
- Neurogenic claudication
- Paraplegia
- Conus Medullaris Syndrome

CHAPTER-IV

MATERIALS AND METHODS

A prospective open labeled randomized clinical study of Thandaga Vatham is carried out in Post Graduate Department of Pothu Maruthuvam, Government Siddha Medical College and Hospital, Palayamkottai.

Selection of the Cases:

Totally 40 cases were selected.Out of 40, 20 cases were selected as Inpatients and 20 cases treated as Out patients. These cases were selected from the Outpatient Department of Pothu Maruthuvam according to the inclusion and exclusion criteria.

Aetiological factors:

The seasonal variations and precipitating factors like emotional stress and strain, trauma, occupation and food habits were enquired and recorded. The socio economic status, family history and other significant diseases treated already, were thoroughly registered.

Inclusion criteria:

- Age: 30-60years.
- Sex: Both sex.
- Pain in low back area, radiating pain to buttocks and lower limbs, tingling sensation.
- Stiffness present in the low back area.
- Exacerbation of pain on movements.
- Pain increased on forward bending.
- Patient willing to undergo radiological and provide blood and urine samples for laboratory investigation.
- Patient willing to sign the informed consent stating that he / she will consciously stick to the treatment during 30 days but can opt out of the trial of his / her conscious discretion.
- Back pain functional scale score should be below 30.

Exclusion criteria:

- Age below 30 years and above 60 years
- Diabetes mellitus
- Auto immune disease like SLE, RA
- Chronic kidney disease
- Fracture of spine
- Tuberculosis of spine
- Congential spino vertebral deformities
- Cardiac disease
- Endocrine disorders
- Malignancy
- Systemic hypertension
- Pregnancy and lactation
- Osteomyelitis
- Liver disorder
- Chronic alcoholic and smokers

Diagnosis:

The diagnosis is made by following Siddha diagnosis methods:

- Poriyal aridhal
- Pulanal aridhal
- Vinadhal
- Envagai thervugal
- Udal thathukkal
- Kaalam
- Nilam

Haematological Investigations:

- HB%
- Total WBC Count
- Differential Count
- Erythrocyte Sedimentation Rate
- Blood Sugar R/PP/F

- Blood Urea
- Serum Cholesterol
- Serum Creatinine
- Serum Uric Acid

Urine analysis:

a) Albumin
b) Sugar
c) Deposits

Specific Investigations:

a) RA factor
b) ASO titre
c) CRP

Radiological Investigations:

- X-Ray of Lumbar Spine (AP and lateral view)

Assessment of result:

The results were assessed on the basis of symptomatic relief, improvement in back pain functional assessment scale.

The difference in the score before and after treatment represents the improvement in the treatment.

Further the biochemical, pharmacological and acute toxicity studies were done in Government Siddha Medical College, Palayamkottai and K.M. College of Pharmacy, Madurai, Tamilnadu.

Statistical Analysis:

Data were analysed using student's paired t, test using the prism graph pad software. The result were expressed as Mean ± Standard Deviation and P Values <0.001 was observed as statistically significant.

Treatment:

The clinical trial drug **"VAEPPAM PATTAI KUDINEER"** 50ml twice a day after food for 30 days till the end of the course.

All the patients admitted for the study were given uniformly regular hospital diet.

After discharge all the patients were advised to attend the Out patient Department of Pothu Maruthuvam, Government Siddha Medical College and Hospital, Palayamkottai for further follow up.

CHAPTER-V

RESULTS AND OBSERVATIONS

The results were observed regarding the following criteria by clinical trial study on 40 patients. 20 Out patients and 20 In patients of both sex. The criteria were.

1. Age Distribution
2. Sex Distribution
3. Kaalam
4. Paruvakaalam
5. Thinai
6. Constitution of body
7. Gunam
8. Religion
9. Socio-Economical Status
10. Food Habits
11. Family History
12. Occupation
13. Aetiological Factors
14. Mode of Onset
15. Duration of Illness
16. Clinical Manifestation
17. Kanmenthiriyam
18. Gnanendrium
19. Kosam
20. Condition of Mukkutram
    a). Vatham
    b). Pitham
    c). Kapham
21. Involvement of Udal Thathukkal
22. Conditions of Envagai Thervugal
23. Neer Kuri
24. Nei Kuri
25. Radiological Findings
26. Back Pain Functional Score Scale
27. Gradation of results

1. AGE DISTRIBUTION

Table-1 Illustrates the distribution of age and its percentage.

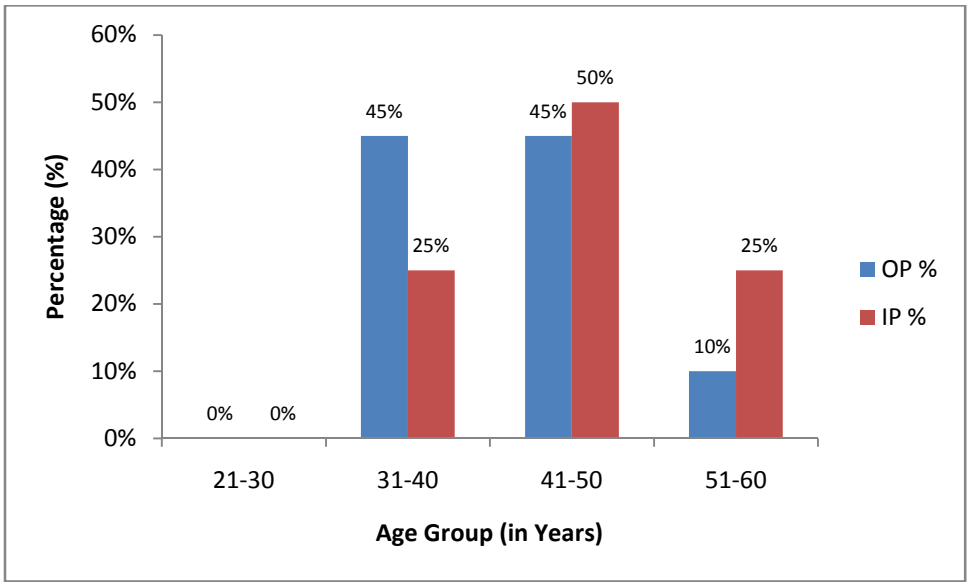
TABLE-1

AGE DISTRIBUTION

Sl. No.	Age group (In years)	Out Patients (OP)		In Patients (IP)	
		No. of cases	Percentage (%)	No. of cases	Percentage (%)
1.	21-30	-	-	-	-
2.	31-40	9	45%	5	25%
3.	41-50	9	45%	10	50%
4.	51-60	2	10%	5	25%
	Total	**20**	**100%**	**20**	**100%**

FIGURE-1

AGE DISTRIBUTION



From the above table, it is observed that the highest incidence of Thandaga Vatham in 20 Out patient is among the age group of 51-60 with 40% and among 20 In patients also in the age group of 51-60 with 65%.

2. SEX DISTRIBUTION

Table-2 Illustrates the distribution of sex and its percentage.

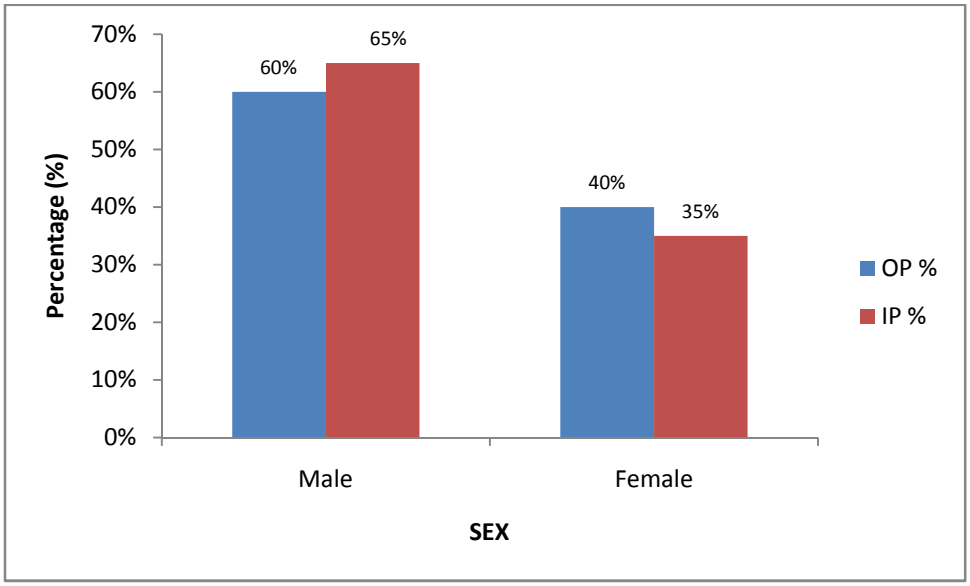
TABLE-2

SEX DISTRIBUTION

Sl. No.	Sex	Out Patients (OP)		In Patients (IP)	
		No. of cases	Percentage (%)	No. of cases	Percentage (%)
1.	Male	12	60%	13	65%
2.	Female	8	40%	7	35%
	Total	**20**	**100%**	**20**	**100%**

FIGURE-2

SEX DISTRIBUTION



From the above table, it is observed that among 20 Out patients 60% were males and 40% were females and among 20 In patients 35% were males and 65% were females.

3. KAALAM

Table-3 Illustrates the distribution of kaalam and its percentage.

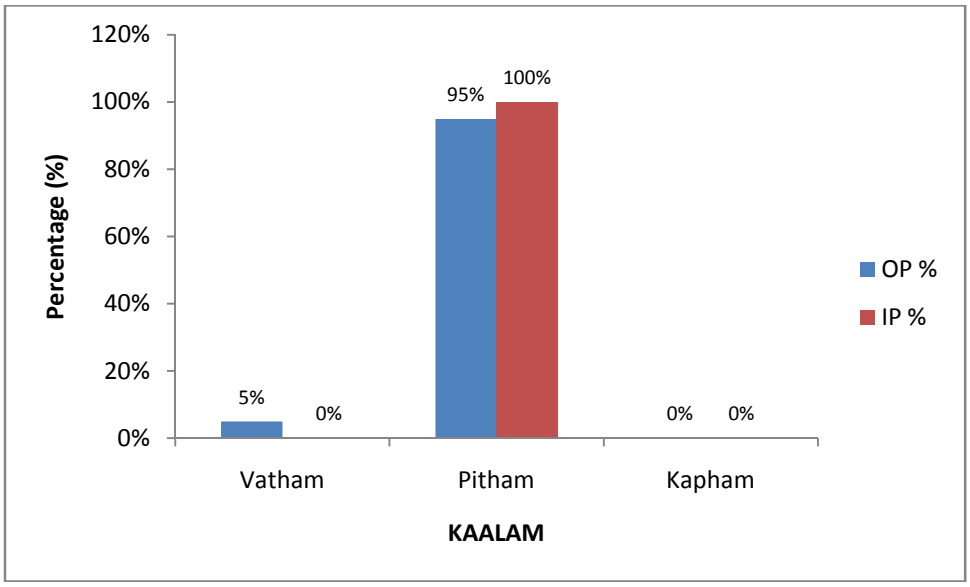
TABLE-3

DISTRIBUTION OF KAALAM

Sl. No.	Kaalam	Out Patients (OP)		In Patients (IP)	
		No. of cases	Percentage (%)	No. of cases	Percentage (%)
1.	Vatham	1	5%	-	-
2.	Pitham	19	95%	20	100%
3.	Kapham	-	-	-	-
	Total	**20**	**100%**	**20**	**100%**

FIGURE-3

DISTRIBUTION OF KAALAM



From the above table, it is observed that the highest incidence of Thandaga Vatham among 20 Out patients is in Pitha Kaalam with 95% and among 20 In patients, is also Pitha Kaalam with 100%.

4. PARUVA KAALAM

Table-4 Illustrates the distribution of paruva kaalam and its percentage.

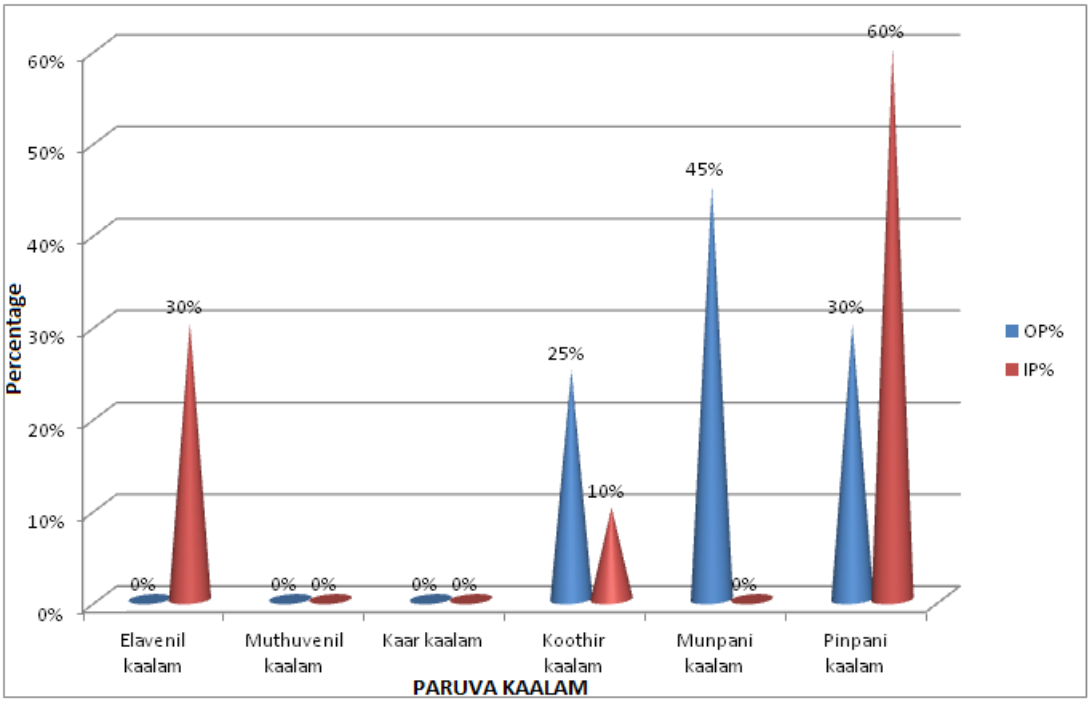
TABLE-4

DISTRIBUTION OF PARUVA KAALAM

Sl. No.	Paruva Kaalam	Out Patients (OP)		In Patients (IP)	
		No. of cases	Percentage (%)	No. of cases	Percentage (%)
1.	Elavenil Kaalam	-	-	6	30%
2.	Muthuvenil Kaalam	-	-	-	-
3.	Kaar Kaalam	-	-	-	-
4.	Koothir Kaalam	5	25%	2	10%
5.	Munpani Kaalam	9	45%	-	-
6.	Pinpani Kaalam	6	30%	12	60%
	Total	**20**	**100%**	**20**	**100%**

FIGURE-4

DISTRIBUTION OF PARUVA KAALAM



From the above table, it is observed that the highest incidence of Thandaga Vatham among 15 Out patients is in Munpani Kaalam and among 17 In patients is in Pinpani Kaalam.

5. THINAI

Table-5 Illustrates the distribution of thinai and its percentage.

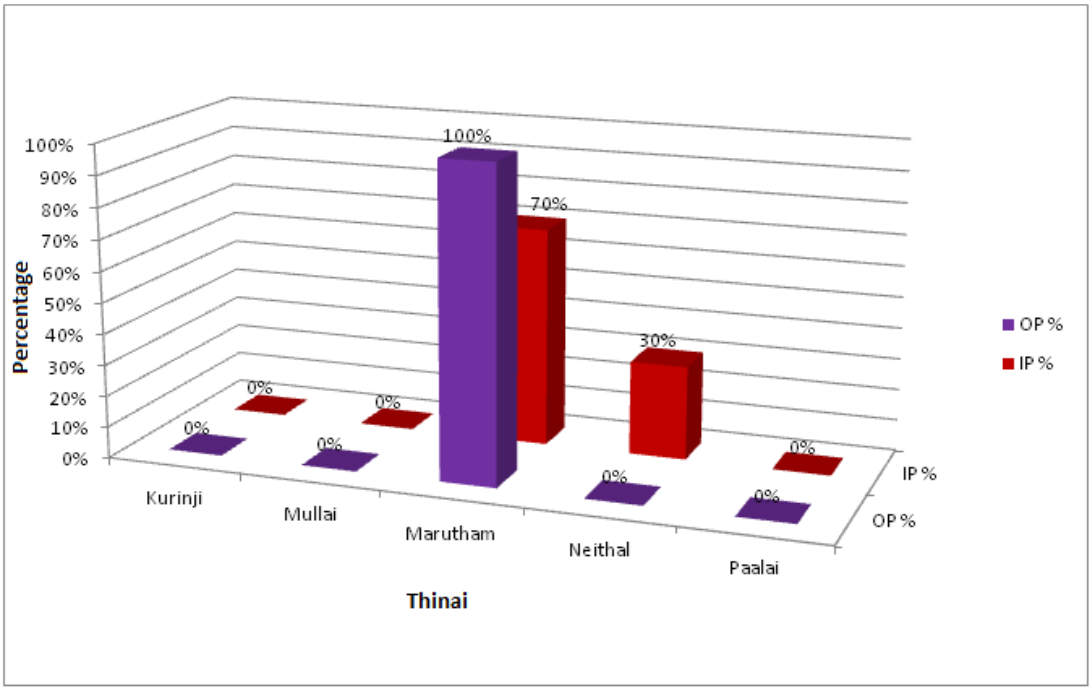
TABLE-5

DISTRIBUTION OF THINAI

Sl. No.	Thinai	Out Patients (OP)		In Patients (IP)	
		No. of cases	Percentage (%)	No. of cases	Percentage (%)
1.	Kurinji	-	-	-	-
2.	Mullai	-	-	-	-
3.	Marutham	20	100%	14	70%
4.	Neithal	-	-	6	30%
5.	Paalai	-	-	-	-
	Total	**20**	**100%**	**20**	**100%**

FIGURE-5

DISTRIBUTION OF THINAI



From the above table, it is observed that highest incidence of Thandaga Vatham among 20 Out patients were in the Marutham Thinai with 100% and among 20 In Patients also in Marutham Thinai with 70%.

6. CONSTITUTION OF BODY

Table-6 Illustrates the distribution of constitution of the body and its percentage.

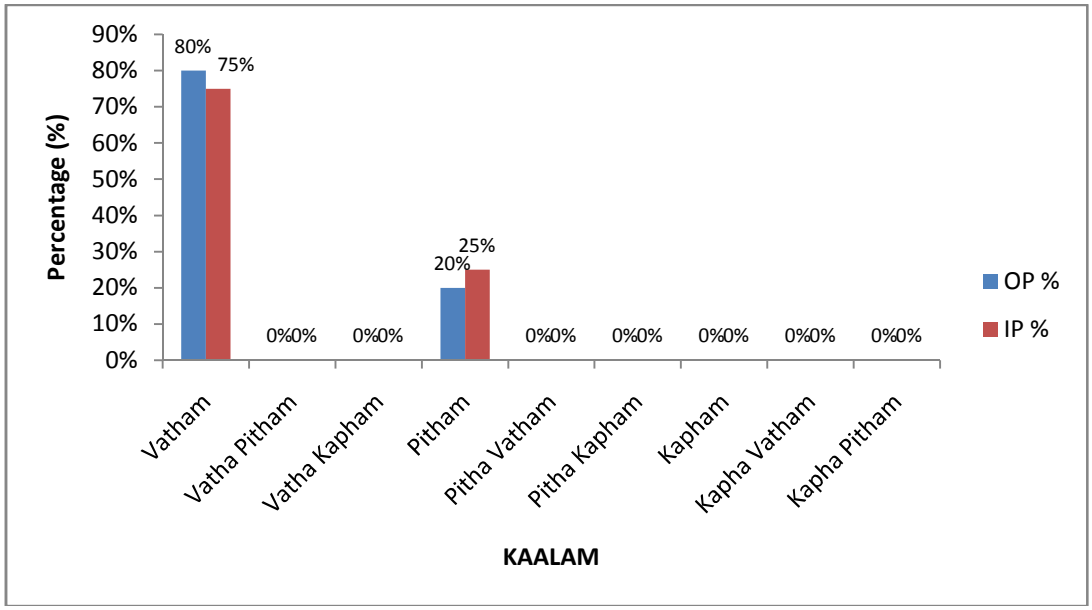
TABLE-6

DISTRIBUTION OF CONSTITUTION OF BODY

Sl. No.	Constitution of body	Out Patients (OP)		In Patients (IP)	
		No. of cases	Percentage (%)	No. of cases	Percentage (%)
1.	Vatham	16	80%	15	75%
2.	Vatha Pitham	-	-	-	-
3.	Vatha Kapham	-	-	-	-
4.	Pitham	4	20%	5	25%
5.	Pitha Vatham	-	-	-	-
6.	Pitha Kapham	-	-	-	-
7.	Kapham	-	-	-	-
8.	Kapha Vatham	-	-	-	-
9.	Kapha Pitham	-	-	-	-
	Total	**20**	**100%**	**20**	**100%**

FIGURE-6

DISTRIBUTION OF CONSTITUTION OF BODY



From the above table, it is observed that the highest incidence of Thandaga Vatham among 20 Out patients is Vatha Thegi with 60% and among 20 In patients is also Vatha Thegi with 50%.

7. GUNAM

Table-7 Illustrates the distribution of gunam and its percentage.

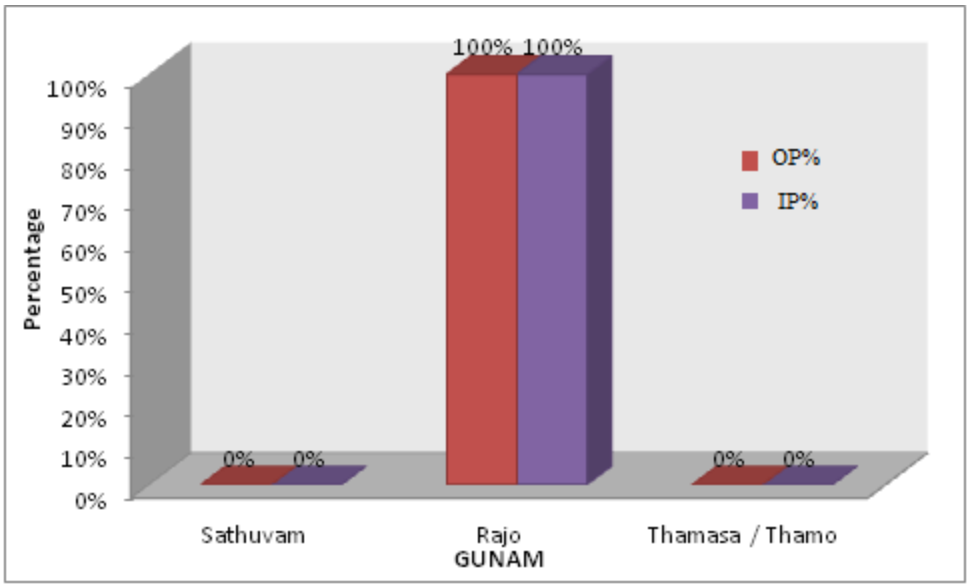
TABLE-7

DISTRIBUTION OF GUNAM

Sl. No.	Gunam	Out Patients (OP)		In Patients (IP)	
		No. of cases	Percentage (%)	No. of cases	Percentage (%)
1.	Sathuvam	-	-	-	-
2.	Rajo	20	100%	20	100%
3.	Thamasa / Thamo	-	-	-	-
	Total	**20**	**100%**	**20**	**100%**

FIGURE-7

DISTRIBUTION OF GUNAM



From the above table, it is observed that the highest incidence of Thandaga Vatham among 20 Out patients and 20 In patients with cent percent belongs to Rajo Gunam.

8. RELIGION

Table-8 Illustrates the distribution of religion and its percentage.

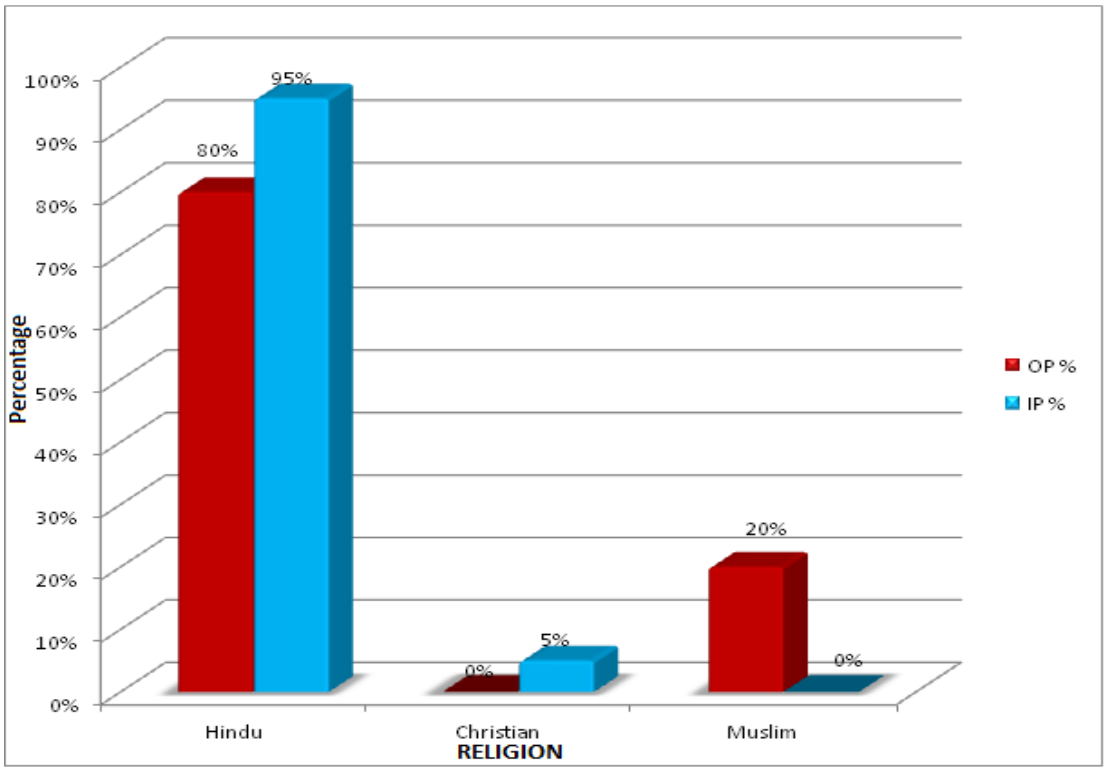
TABLE-8

DISTRIBUTION OF RELIGION

Sl. No.	Religion	Out Patients (OP)		In Patients (IP)	
		No. of cases	Percentage (%)	No. of cases	Percentage (%)
1.	Hindu	16	80%	19	95%
2.	Christian	-	-	1	5%
3.	Muslim	4	20%	-	-
	Total	**20**	**100%**	**20**	**100%**

FIGURE-8

DISTRIBUTION OF RELIGION



From the above table, it is observed that among 20 Out patients 80% were Hindus, 15% were Christians and 20% were Muslims and among 20 In patients 95% were Hindus, 5% were Christians.

9. SOCIO-ECONOMICAL STATUS

Table-9 Illustrates the distribution of socio-economical status and its percentage.

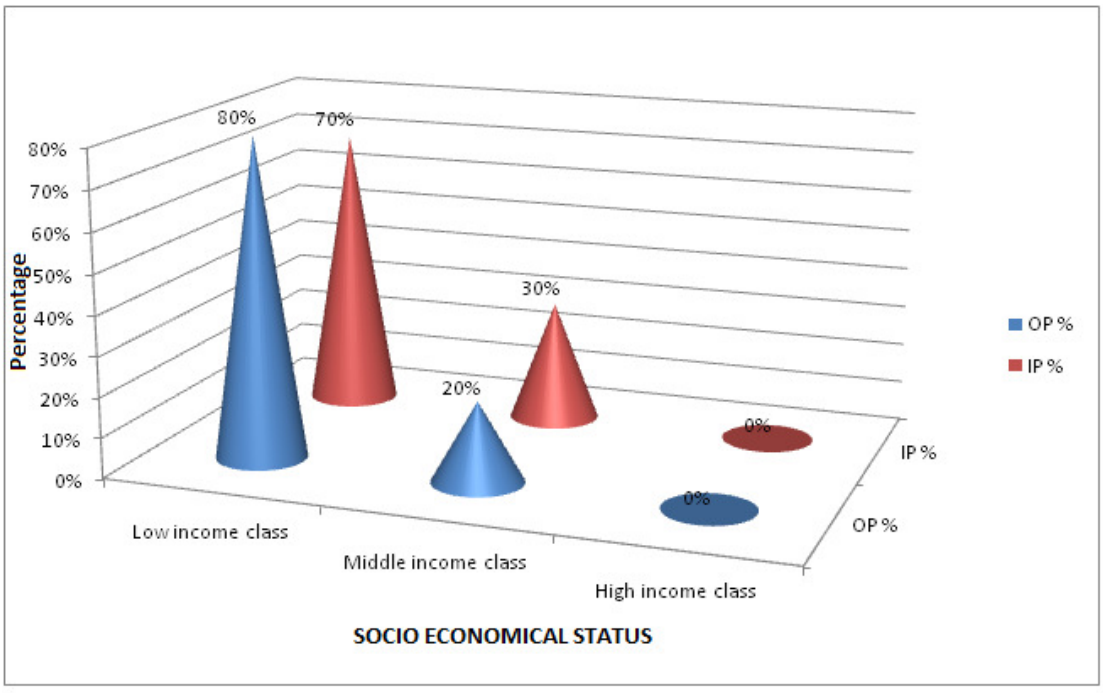
TABLE-9

DISTRIBUTION OF SOCIO-ECONOMICAL STATUS

Sl. No.	Socio-Economical Status	Out Patients (OP)		In Patients (IP)	
		No. of cases	Percentage (%)	No. of cases	Percentage (%)
1.	High income class	-	-	-	-
2.	Middle income class	4	20%	6	30%
3.	Low income class	16	80%	14	70%
	Total	**20**	**100%**	**20**	**100%**

FIGURE-9

DISTRIBUTION OF SOCIO-ECONOMICAL STATUS



From the above table, it is observed that the highest incidence of Thandaga Vatham among 20 Out patients is in Low income class with 80% and among 20 In patients is in Low Income class with 70%.

10. FOOD HABITS

Table-10 Illustrates the distribution of diet and its percentage.

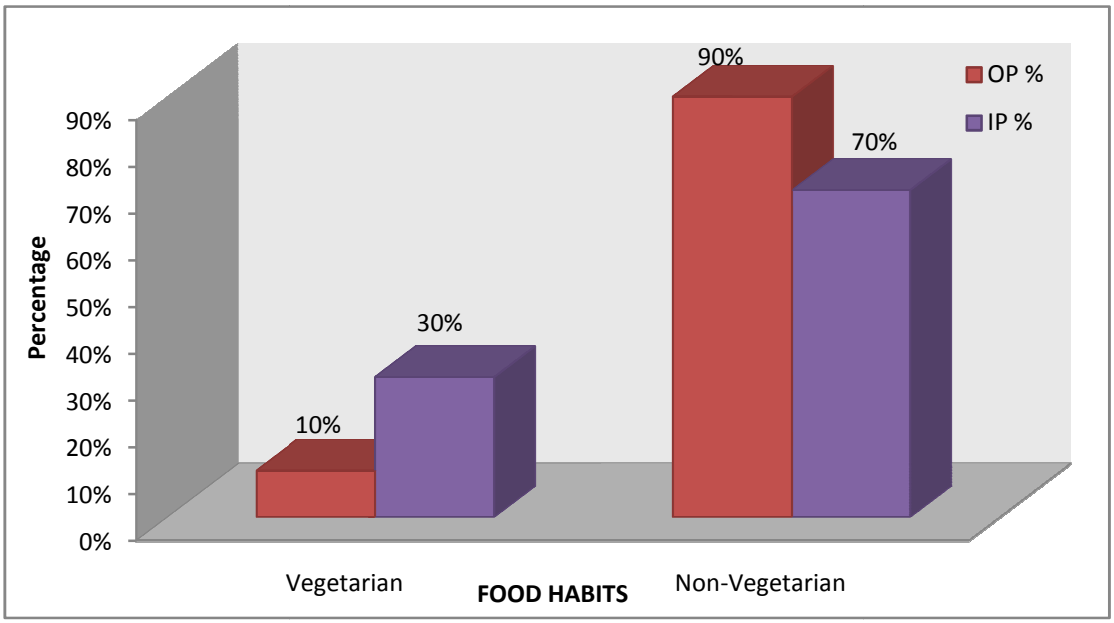
TABLE-10

DISTRIBUTION OF FOOD HABITS

Sl. No.	Food Habits	Out Patients (OP)		In Patients (IP)	
		No. of cases	Percentage (%)	No. of cases	Percentage (%)
1.	Vegetarian	2	10%	6	30%
2.	Non-Vegetarian	18	90%	14	70%
	Total	**20**	**100%**	**20**	**100%**

FIGURE-10

DISTRIBUTION OF FOOD HABITS



From the above table, it is observed that the highest incidence of Thandaga Vatham among 20 Out patients isin Non-Vegetarians with 90% and among 20 In patients is also in Non-Vegetarians with 70%.

11. FAMILY HISTORY

Table-11 Illustrates the family history and its percentage.

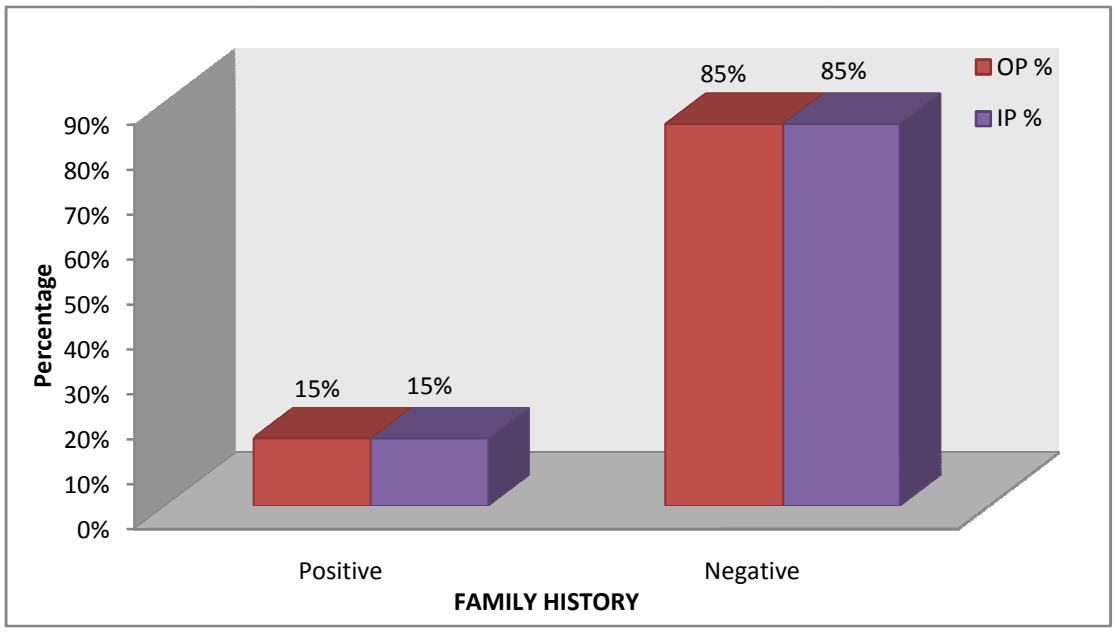
TABLE-11

FAMILY HISTORY

Sl. No.	Family History	Out Patients (OP)		In Patients (IP)	
		No. of cases	Percentage (%)	No. of cases	Percentage (%)
1.	Positive	3	15%	3	15%
2.	Negative	17	85%	17	85%
	Total	**20**	**100%**	**20**	**100%**

FIGURE-11

FAMILY HISTORY



From the above table, it is observed that among 20 Out patients and 20 In patients, 15% have positive family history and 85% don't have positive family history.

12. OCCUPATION

Table-12 Illustrates the occupation and its percentage.

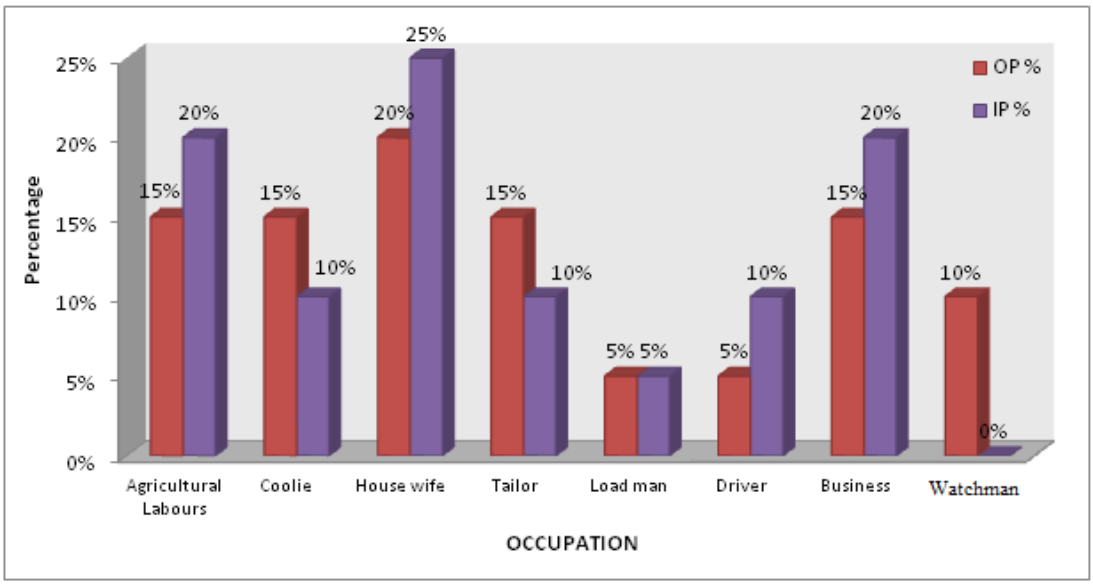
TABLE-12

OCCUPATION

Sl. No.	Occupation	Out Patients (OP)		In Patients (IP)	
		No. of cases	Percentage (%)	No. of cases	Percentage (%)
1.	Agricultural Labours	3	15%	4	20%
2.	Coolie	3	15%	2	10%
3.	House wife	4	20%	5	25%
4.	Tailor	3	15%	2	10%
5.	Load man	1	5%	1	5%
6.	Driver	1	5%	2	10%
7.	Business	3	15%	4	20%
8.	Watchman	2	10%	-	-
	Total	**20**	**100%**	**20**	**100%**

FIGURE-12

DISTRIBUTION OF OCCUPATION



From the above table, it is observed that the highest incidence of Thandaga Vatham among 20 Out patients were house wives with 20% and among 20 In patients is also house wives with 25%.

13. AETIOLOGICAL FACTORS

Table-13 ISllustrates the aetiological factors and its percentage.

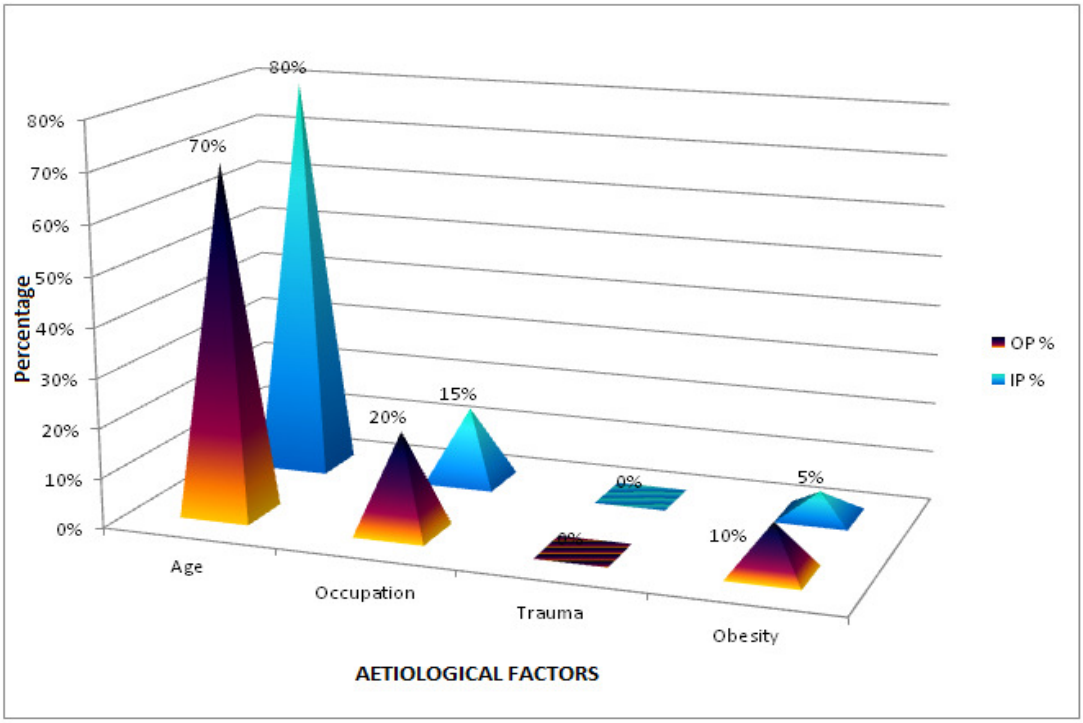
TABLE-13

AETIOLOGICAL FACTORS

Sl. No.	Aetiological Factors	Out Patients (OP)		In Patients (IP)	
		No. of cases	Percentage (%)	No. of cases	Percentage (%)
1.	Age (30-60 years)	14	70%	16	80%
2.	Occupation	4	20%	3	15%
3.	Trauma	-	-	-	-
4.	Obesity	2	10%	1	5%
	Total	**20**	**100%**	**20**	**100%**

FIGURE-13

AETIOLOGICAL FACTORS



From the above table, it is observed that the highest incidence of Thandaga Vatham among 20 Out patients is due to age related aetiological factors with 70% and among 20 In patients is also due to age related aetiological factors with 80%.

14. MODE OF ONSET

Table-14 Illustrates the mode of onset and its percentage.

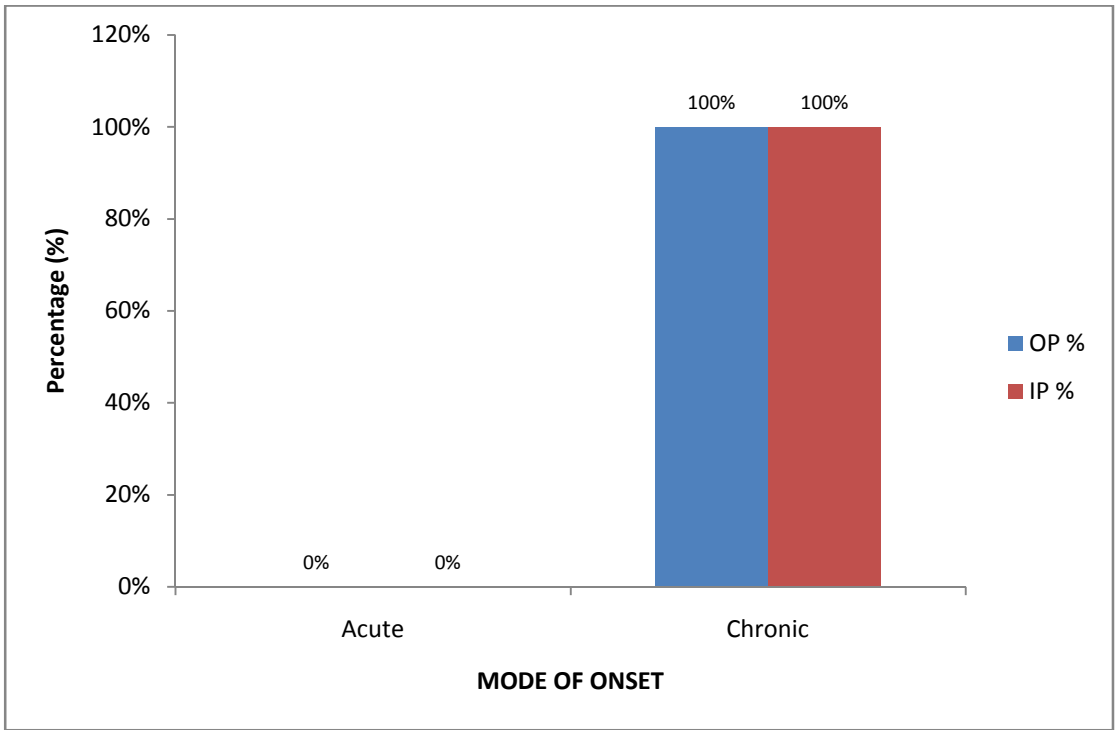
TABLE-14

MODE OF ONSET

Sl. No.	Mode of Onset	Out Patients (OP)		In Patients (IP)	
		No. of cases	Percentage (%)	No. of cases	Percentage (%)
1.	Acute	-	-	-	-
2.	Chronic	20	100%	20	100%
	Total	**20**	**100%**	**20**	**100%**

FIGURE-14

MODE OF ONSET



From the above table, it is observed that among 20 Out patients, 90% were in chronic state and among 20 In patients, 100% were in chronic state.

15. DURATION OF ILLNESS

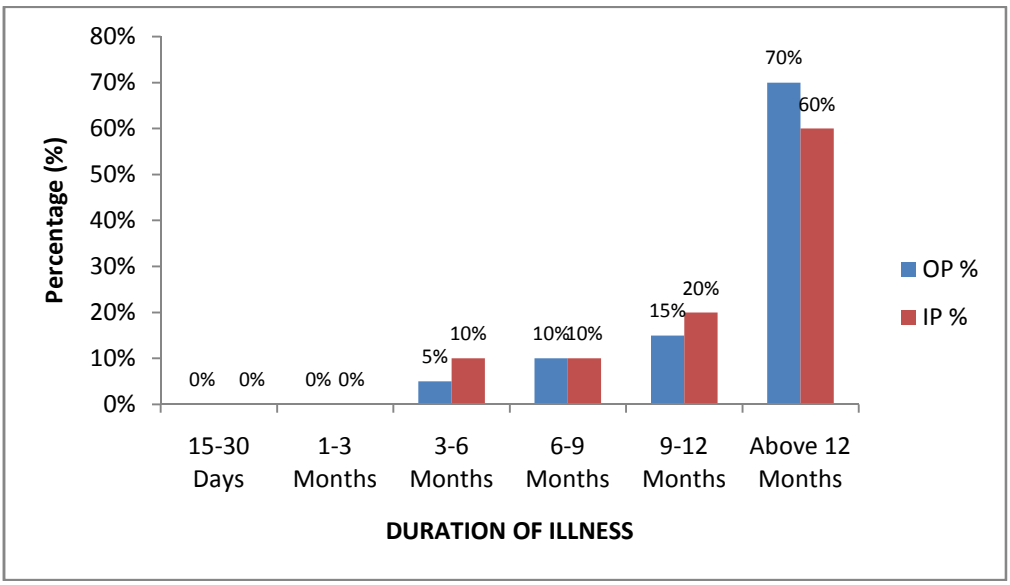
Table-15 Illustrates the duration of illness and its percentage.

TABLE-15
DURATION OF ILLNESS

Sl. No.	Duration of illness	Out Patients (OP)		In Patients (IP)	
		No. of cases	Percentage (%)	No. of cases	Percentage (%)
1.	15-30 Days	-	-	-	-
2.	1-3 Months	-	-	-	-
3.	3-6 Months	1	5%	2	10%
4.	6-9 Months	2	10%	2	10%
5.	9-12 Months	3	15%	4	20%
6.	Above 12 Months	14	70%	12	60%
	Total	**20**	**100%**	**20**	**100%**

FIGURE-15

DURATION OF ILLNESS



From the above table, among 20 Out patients, duration of illness 15% were 15-30 days, 25% were 1-3 months, 15% were 3-6 months, 10% were 6-9 months, 10% were 9-12 months, 25% were above 12 months. Among the 20 In patients, duration of illness 20% were 1-3 months, 25% were 3-6 months, 5% were 6-9 months, 25% were 9-12 months, 25% were above 12 months were observed.

16. CLINICAL MANIFESTATION

Table-16 Illustrates the clinical manifestation and its percentage.

TABLE-16

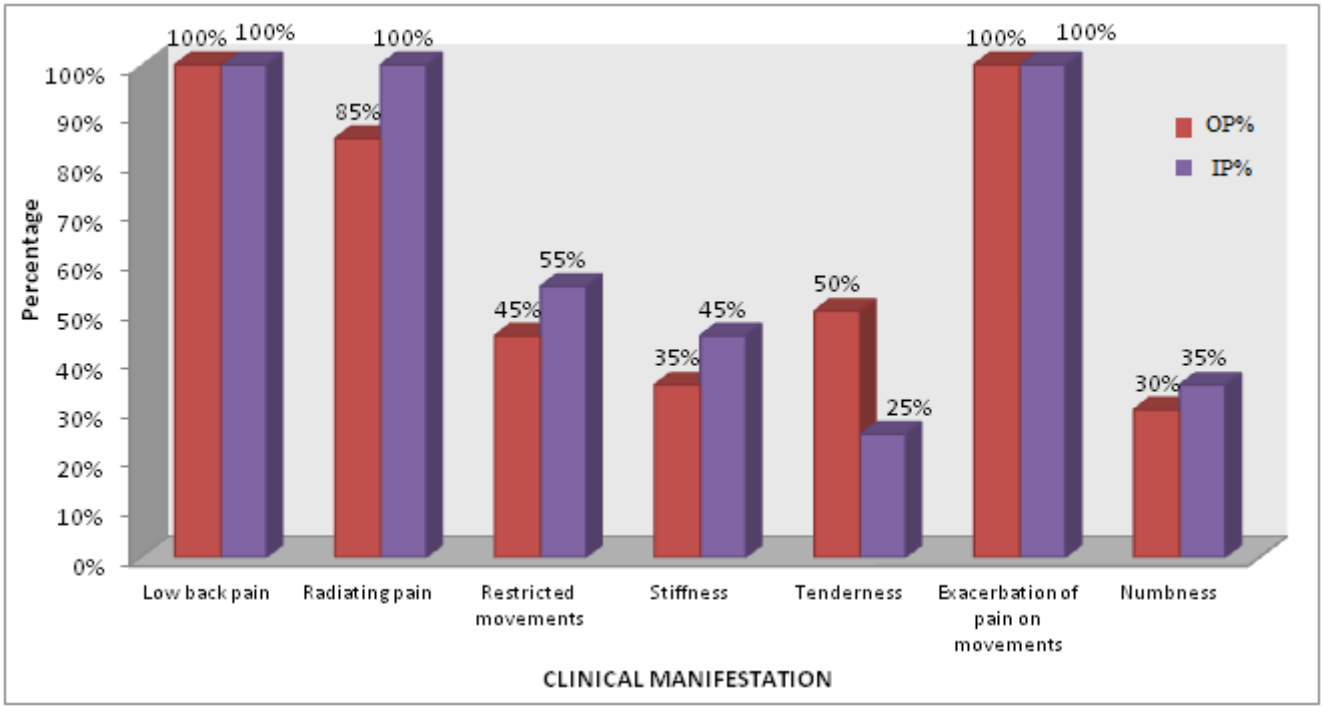
CLINICAL MANIFESTATION

Sl. No.	Clinical Manifestation	Out Patients (OP)		In Patients (IP)	
		No. of cases	Percentage (%)	No. of cases	Percentage (%)
1.	Low back pain	20	100%	20	100%
2.	Radiating pain	17	85%	20	100%
3.	Restricted movements	9	45%	11	55%
4.	Stiffness	7	35%	9	45%
5.	Tenderness	10	50%	5	25%
6.	Exacerbation of pain on movements	20	100%	20	100%
7.	Numbness	6	30%	7	35%

From the above table, it is observed that, among 20 Out patients, 100% of cases have low back pain and exacerbation of pain on movements. 85% have radiating pain, 45% have restricted movements, 35% have stiffness, 35% have tenderness and 30% have numbness. Among20 In patients 100% of cases have low back pain, radiating pain and exacerbation of pain on movements. 55% have restricted movements, 45% have stiffness, 25% have tenderness and 35% have numbness.

FIGURE-16

CLINICAL MANIFESTATION



17. KANMENTHIRIYAM

Table-17 Illustrates the kanmenthiriyam and its percentage.

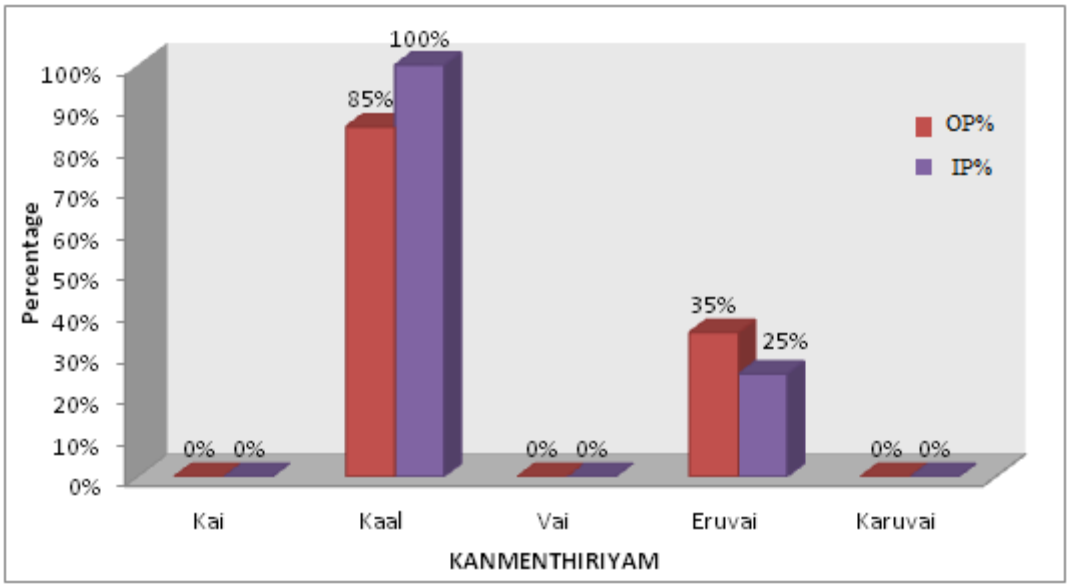
TABLE-17

KANMENTHIRIYAM

Sl. No.	Kanmenthiriyam	Out Patients (OP)		In Patients (IP)	
		No. of cases	Percentage (%)	No. of cases	Percentage (%)
1.	Kai	-	-	-	-
2.	Kaal	17	85%	20	100%
3.	Vai	-	-	-	-
4.	Eruvai	7	35%	5	25%
5.	Karuvai	-	-	-	-

FIGURE-17

KANMENTHIRIYAM



From the above table, it is observed that among 20 Out patients, 85% were affected in Kaal and 35% in Eruvai. Among 20 In patients 100% were affected in Kaal and 25% in Eruvai.

18. GNANENDRIUM

Table-18 Illustrates the gnanendrium and its percentage.

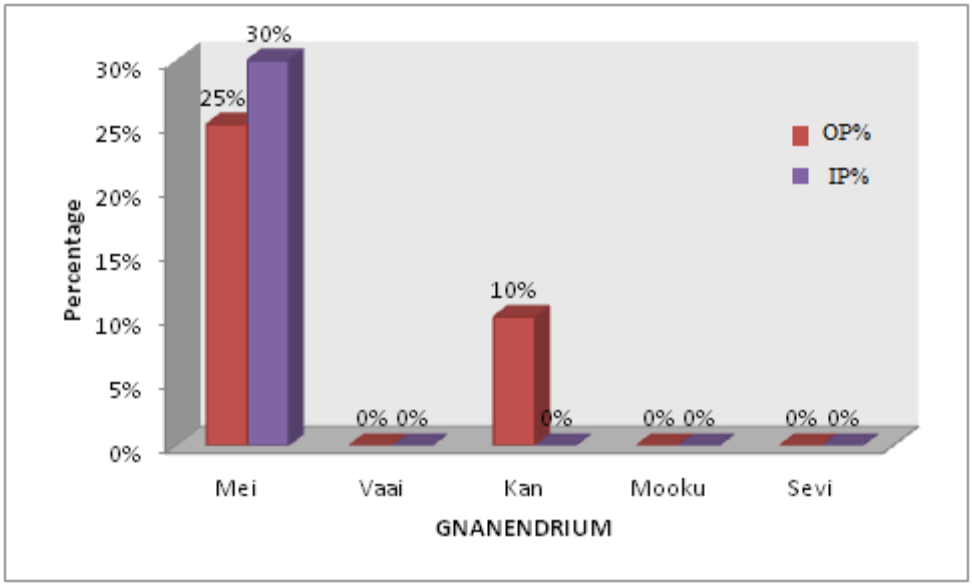
TABLE-18

GNANENDRIUM

Sl. No.	Gnanendrium	Out Patients (OP)		In Patients (IP)	
		No. of cases	Percentage (%)	No. of cases	Percentage (%)
1.	Mei	5	25%	6	30%
2.	Vaai	-	-	-	-
3.	Kan	2	10%	-	-
4.	Mooku	-	-	-	-
5.	Sevi	-	-	-	-

FIGURE-18

GNANENDRIUM



From the above table, it is observed that, among 20 Out patients, 25% were affected in Mei; 10% were affected in Kan. Among 20 In patients 30% were affected in Mei.

19. KOSAM

Table-19 Illustrates the kosam and its percentage.

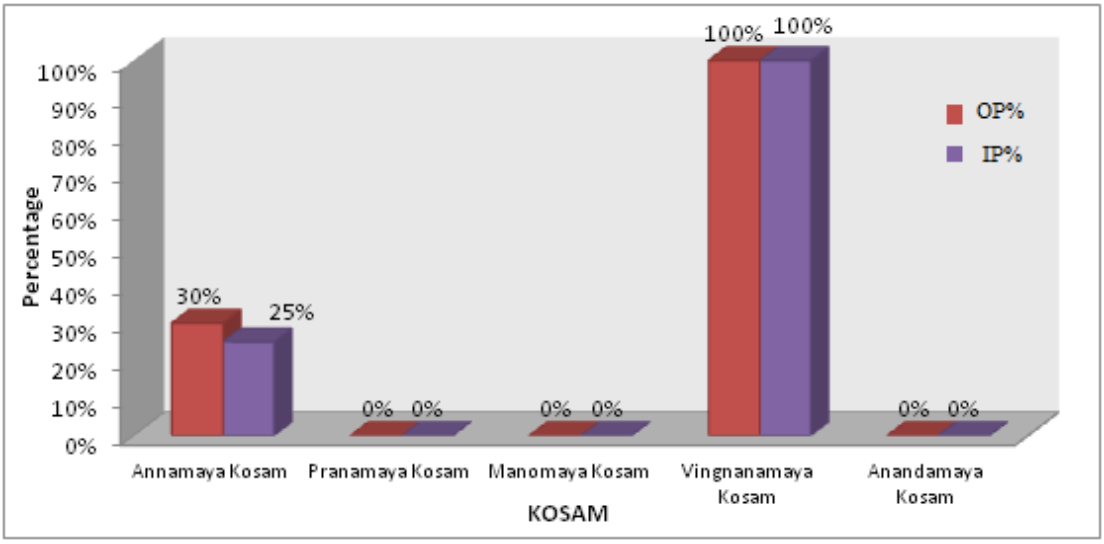
TABLE-19

KOSAM

Sl. No.	KOSAM	Out Patients (OP)		In Patients (IP)	
		No. of cases	Percentage (%)	No. of cases	Percentage (%)
1.	Annamaya Kosam	6	30%	5	25%
2.	Pranamaya Kosam	-	-	-	-
3.	Manomaya Kosam	-	-	-	-
4.	Vingnanamaya Kosam	20	100%	20	100%
5.	Anandamaya Kosam	-	-	-	-

FIGURE-19

KOSAM



From the above table, it is observed that among 20 Out patients 100% were affected withVingnanamaya Kosam and 30% were affected with Annamaya Kosam. Among 20 In patients, 100% were affected withVingnanamaya Kosam and 25% were affected with Annamaya Kosam.

20 (a).CONDITION OF MUKKUTRAM

(a). VATHAM:

Table-20 (a) Illustrates the condition of vatham and its percentage.

TABLE-20 (a)

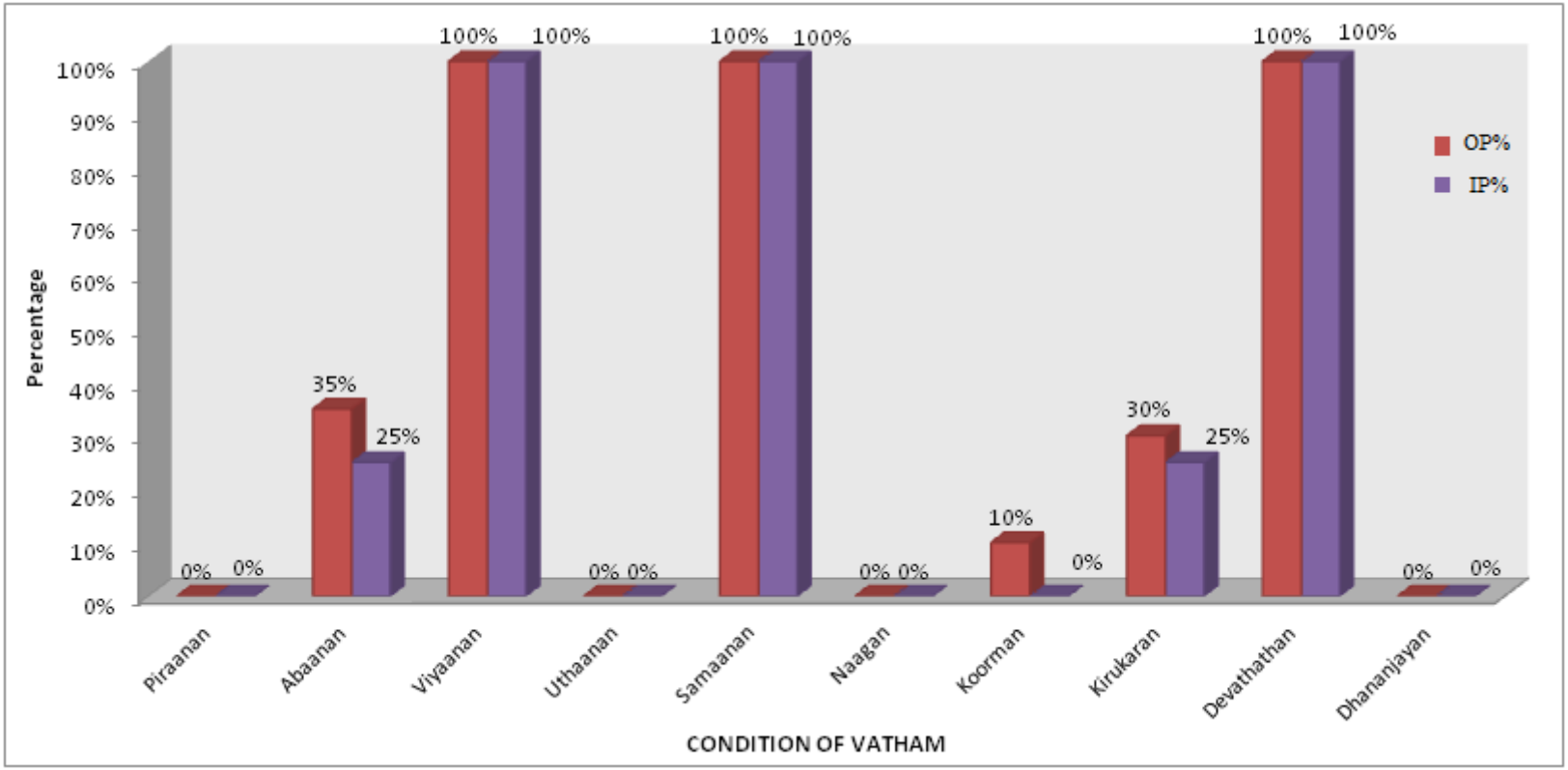
CONDITION OF VATHAM

Sl. No.	Condition of Vatham	Out Patients (OP)		In Patients (IP)	
		No. of cases	Percentage (%)	No. of cases	Percentage (%)
1.	Piraanan	-	-	-	-
2.	Abaanan	7	35%	5	25%
3.	Viyaanan	20	100%	20	100%
4.	Uthaanan	-	-	-	-
5.	Samaanan	20	100%	20	100%
6.	Naagan	-	-	-	-
7.	Koorman	2	10%	-	-
8.	Kirukaran	6	30%	5	25%
9.	Devathathan	20	100%	20	100%
10.	Dhananjayan	-	-	-	-

From the above table, it is observed that among 20 Out patients 100% were affected in Viyaanan, Samaanan and Devathathan; 35% were affected in Abaanan; 10% were affected in Koorman; 30% were affected in Kirukaran; Among 20 In patients 100% were affected in Viyaanan, Samaanan and Devathathan; 25% were affected in Abaanan.

FIGURE-20 (a)

CONDITION OF VATHAM



20 (b).PITHAM

Table-20 (b) Illustrates the condition of pitham and its percentage.

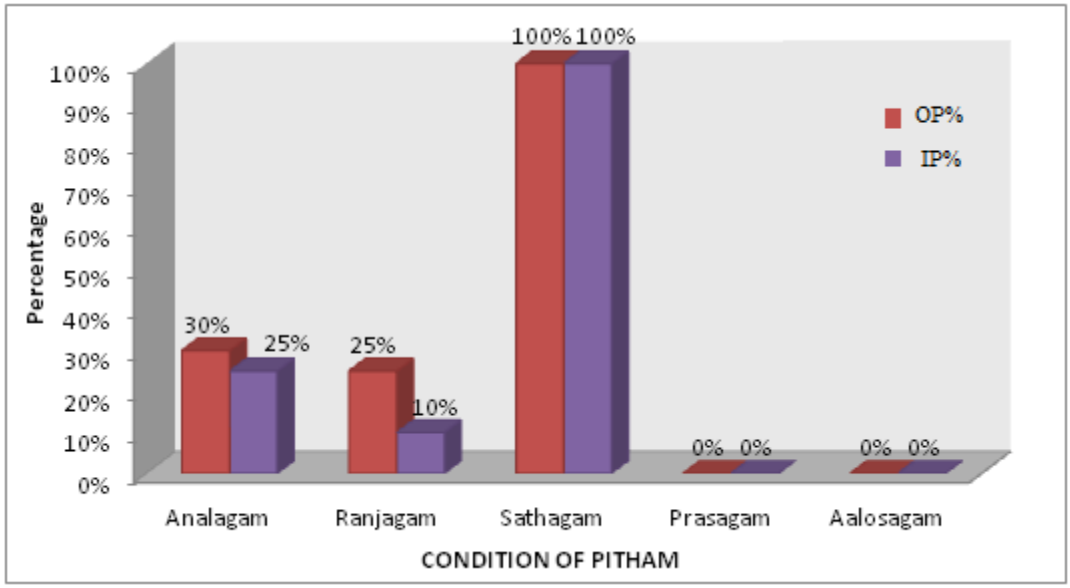
TABLE-20 (b)

CONDITION OF PITHAM

Sl. No.	Condition of Pitham	Out Patients (OP)		In Patients (IP)	
		No. of cases	Percentage (%)	No. of cases	Percentage (%)
1.	Analagam	6	30%	5	25%
2.	Ranjagam	5	25%	2	10%
3.	Sathagam	20	100%	20	100%
4.	Prasagam	-	-	-	-
5.	Aalosagam	-	-	-	-

FIGURE-20 (b)

CONDITION OF PITHAM



From the above table, it is observed that among 20 Out patients, 100% were affected in Sathagam; 30% were affected in Analagam; 25% were affected in Ranjagam; Among 20 In patients, 100% were affected in Sathagam; 25% were affected in Analagam; 10% were affected in Ranjagam.

20 (c).KAPHAM

Table-20 (c) Illustrates the condition of kapham and its percentage.

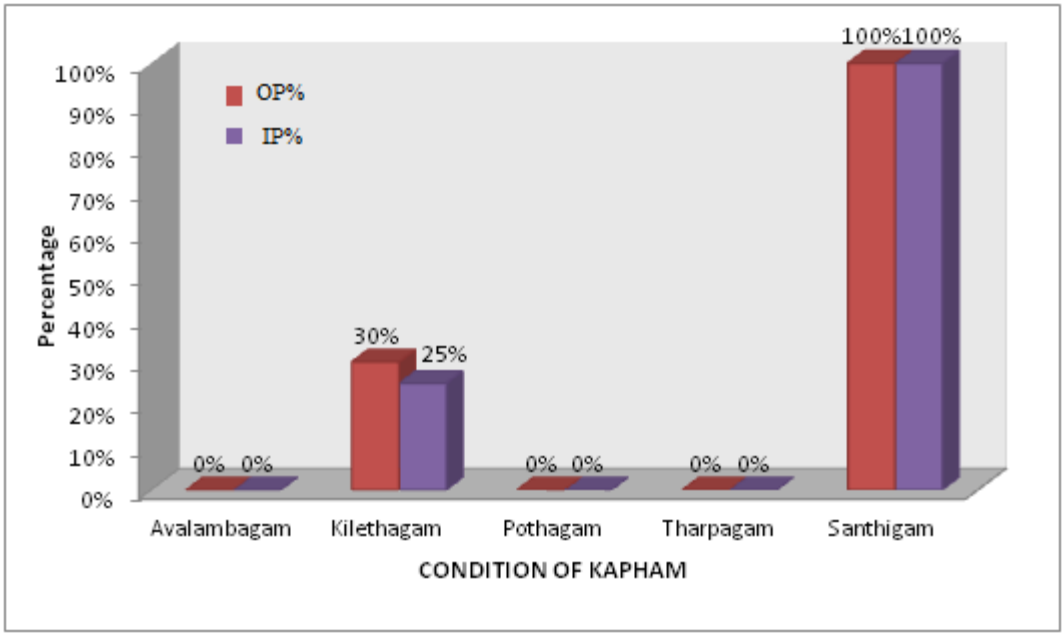
TABLE-20 (c)

CONDITION OF KAPHAM

Sl. No.	Condition of Kapham	Out Patients (OP)		In Patients (IP)	
		No. of cases	Percentage (%)	No. of cases	Percentage (%)
1.	Avalambagam	-	-	-	-
2.	Kilethagam	6	30%	5	25%
3.	Pothagam	-	-	-	-
4.	Tharpagam	-	-	-	-
5.	Santhigam	20	100%	20	100%

FIGURE-20 (c)

CONDITION OF KAPHAM



From the above table, it is observed that among 20 Out patients, 100% were affected in Santhigam; 30% were affected in Kilethagam. Among 20 In patients, 100% were affected in Santhigam; 25% were affected in Kilethagam.

21. INVOLVEMENT OF UDAL THATHUKKAL

Table-21 Illustrates the involvement of udal thathukkal and its percentage.

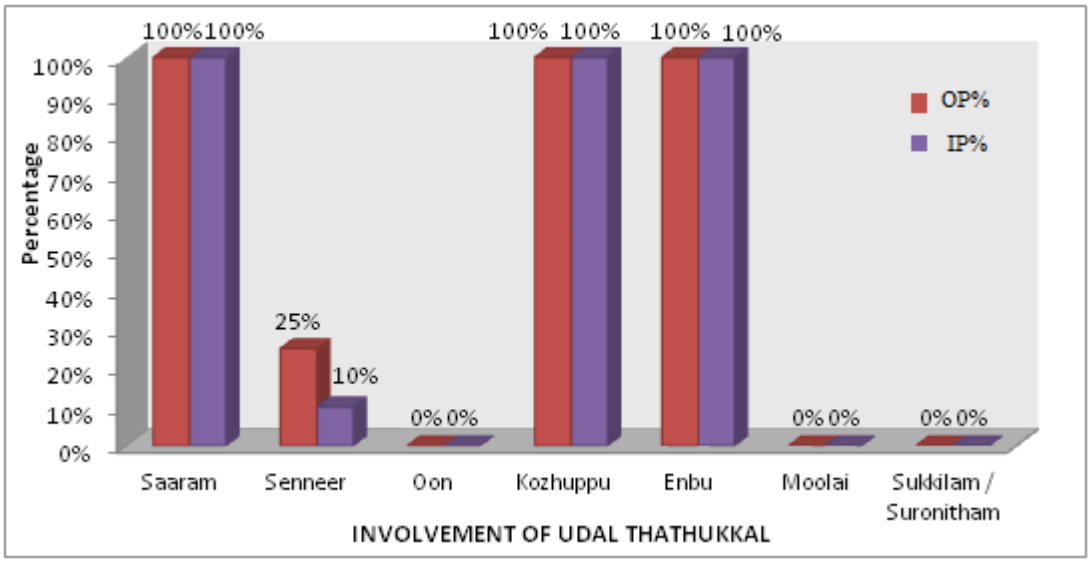
TABLE-21

INVOLVEMENT OF UDAL THATHUKKAL

Sl. No.	Involvement of Udal Thathukkal	Out Patients (OP)		In Patients (IP)	
		No. of cases	Percentage (%)	No. of cases	Percentage (%)
1.	Saaram	20	100%	20	100%
2.	Senneer	5	25%	2	10%
3.	Oon	-	-	-	-
4.	Kozhuppu	20	100%	20	100%
5.	Enbu	20	100%	20	100%
6.	Moolai	-	-	-	-
7.	Sukkilam / Suronitham	-	-	-	-

FIGURE-21

INVOLVEMENT OF UDAL THATHUKKAL



From the above table, it is observed that among 20 Out patients and 20 In patients cent percent were affected in Saaram, Kozhuppu, Enbu. Among 20 Out patients, 25% were affected in Senneer and in 20 In patients, 10% were affected in Senneer.

22. CONDITIONS OF ENVAGAI THERVUGAL

Table-22 Illustrates the envagai thervugal and and its percentage.

TABLE-22

CONDITIONS OF ENVAGAI THERVUGAL

Sl. No.	Conditions of Envagai Thervugal	Out Patients (OP)		In Patients (IP)	
		No. of cases	Percentage (%)	No. of cases	Percentage (%)
1.	Naadi (Thontha Naadi)				
	1). Vatha Pitham	16	80%	12	60%
	2). Vatha Kapham	-	-	2	10%
	3). Pitha Vatham	4	20%	6	30%
	4). Pitha Kapham	-	-	-	-
	5). Kapha Vatham	-	-	-	-
	6). Kapha Pitham	-	-	-	-
2.	Sparisam	5	25%	6	30%
3.	Naa	-	-	-	-
4.	Niram	-	-	-	-
5.	Mozhi	-	-	-	-
6.	Vizhi	7	35%	2	10%
7.	Malam	7	35%	5	25%
8.	Moothiram	-	-	-	-

From the above table it is observed that among 20 Out patients, 55% have Vatha Pitha Naadi, 25% have Vatha Kapha Naadi and 20% have Pitha Vatha Naadi; 25% were affected in Sparisam; 35% were affected in Vizhi and Malam. Among 20 In patients, 60% have Vatha Pitha Naadi, 10% have Vatha Kapha Naadi and 30% have Pitha Vatha Naadi; 30% were affected in Sparisam; 10% were affected in vizhi; 25% were affected in Malam.

23. NEERKURI

Table-23 Illustrates the neer kuri and its percentage.

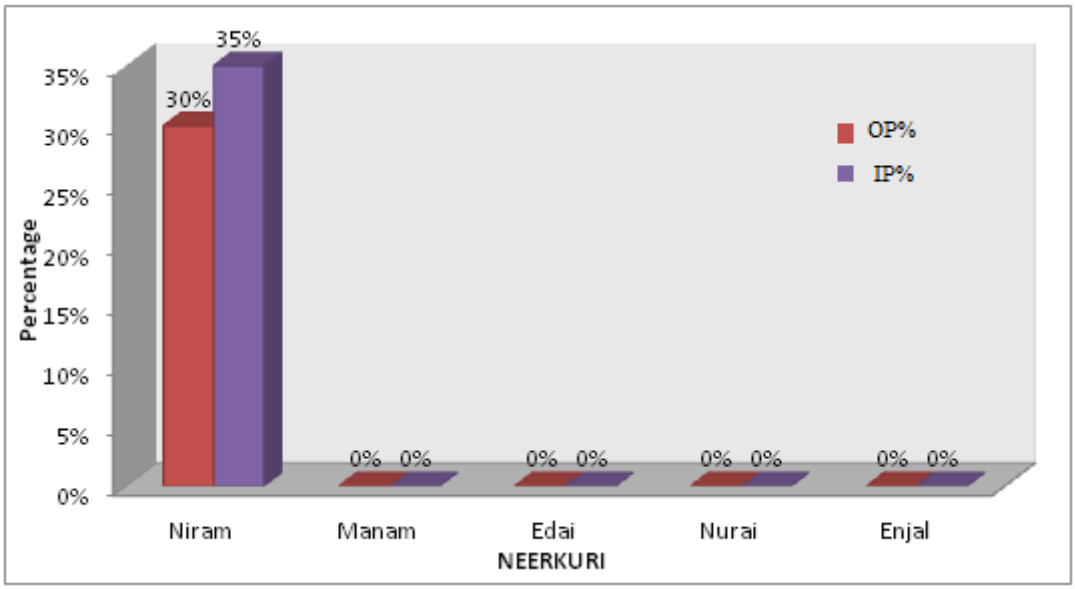
TABLE-23

NEERKURI

Sl. No.	Neer Kuri	Out Patients (OP)		In Patients (IP)	
		No. of cases	Percentage (%)	No. of cases	Percentage (%)
1.	Niram	6	30%	7	35%
2.	Manam	-	-	-	-
3.	Edai	-	-	-	-
4.	Nurai	-	-	-	-
5.	Enjal	-	-	-	-

FIGURE-23

NEERKURI



From the above table, it is observed that among 20 Out patients, 30% were affected in Niram. Among 20 In patients,35% were affected in Niram.

24. NEI KURI

Table-24 Illustrates the neikuri and its percentage.

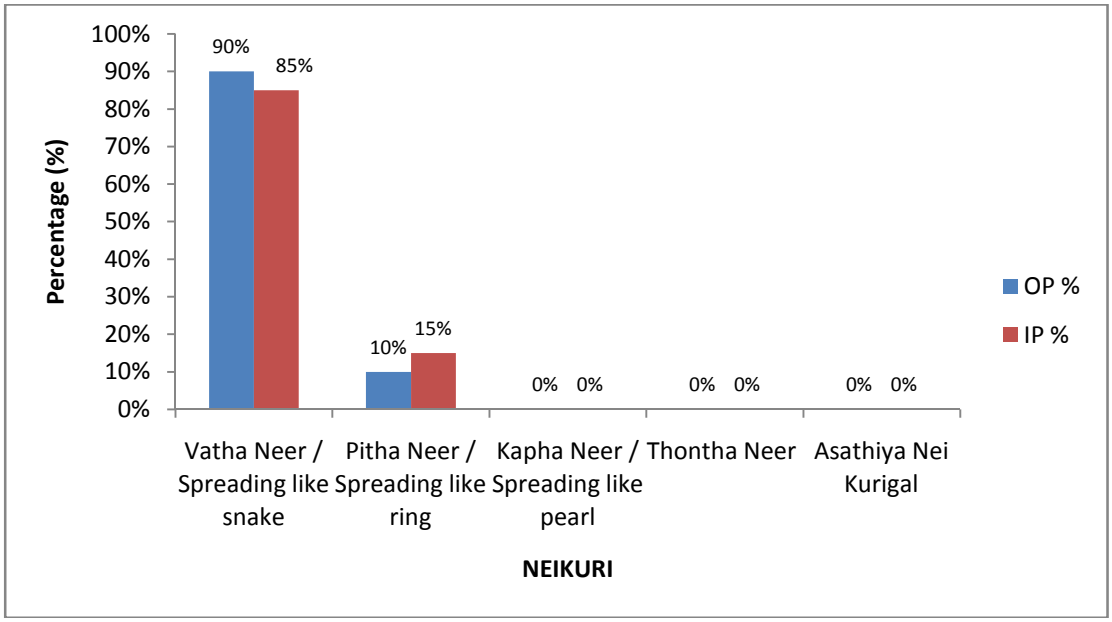
TABLE-24

NEIKURI

Sl. No.	Nei Kuri	Out Patients (OP)		In Patients (IP)	
		No. of cases	Percentage (%)	No. of cases	Percentage (%)
1.	Vatha Neer / Spreading like snake	18	90%	17	85%
2.	Pitha Neer / Spreading like ring	2	10%	3	15%
3.	Kapha Neer / Spreading like pearl	-	-	-	-
4.	Thontha Neer	-	-	-	-
5.	Asathiya Nei Kurigal	-	-	-	-

FIGURE-24

NEIKURI



From the above table, it is observed that among 20 Out patients, 70% have Vatha Neer; 10% Pitha Neer; 10% Kapha Neer and 10% Thontha Neer. Among 20 In patiens, 65% have Vatha Neer; 15% Pitha Neer; 10% Kapha Neer and 10% Thontha Neer.

25. RADIOLOGICAL FINDINGS

Table-25 Illustrates radiological findings and its percentage.

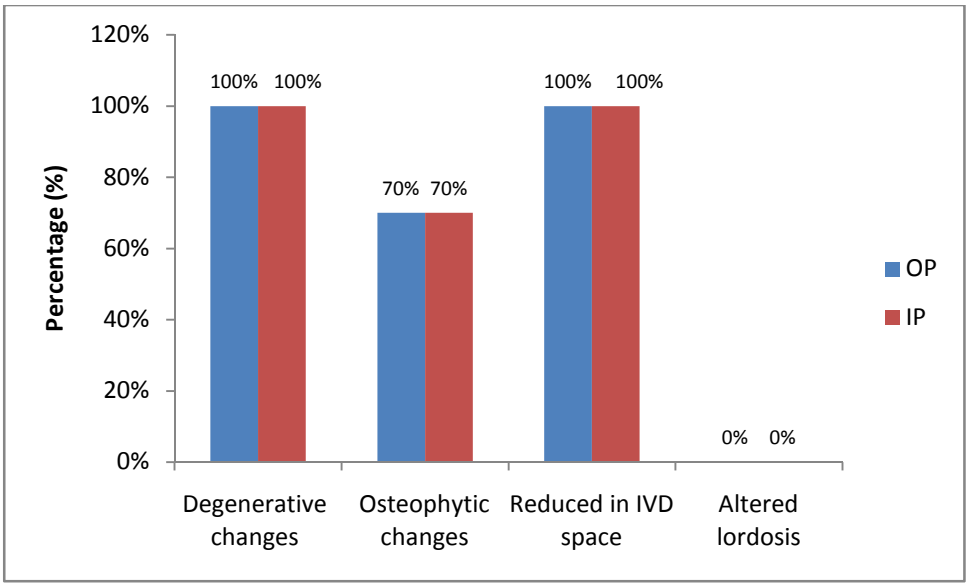
TABLE-25

RADIOLOGICAL FINDINGS

Sl. No.	Radiological Findings	Out Patients (OP)		In Patients (IP)	
		No. of cases	Percentage (%)	No. of cases	Percentage (%)
1.	Degenerative changes	20	100%	20	100%
2.	Osteophytic changes	14	70%	40	70%
3.	Reduced in IVD space	20	100%	20	100%
4.	Altered lordosis	-	0%	-	0%

FIGURE-25

RADILOGICAL FINDINGS



From the above table, it is observed that among 20 Out patients and 20 In patients, cent percent have degenerative and osteophytic changes. Among 20 Out patients, 10% have reduced IVD space. Among 20 In patients, 15% have reduced IVD space; 10% have reduced lordosis.

26. ASSESSMENT OF OUTCOME

(a) Back Pain Functional Scale Score

Table-26 (a) Illustrates backpain functional scale score in percentage.

TABLE-26 (a)

BACK PAIN FUNCTIONAL SCORE SCALE

Sl. No.	Assessment of Outcome (Pain Score)	Before Treatment				After Treatment			
		Out Patients (OP)		In Patients (IP)		Out Patients (OP)		In Patients (IP)	
		No. ofcases	Percentage (%)	No. of cases	Percentage (%)	No. of cases	Percentage (%)	No. of cases	Percentage (%)
1.	≤30	20	100%	20	100%	2	10%	2	10%
2.	31-40	-	-	-	-	2	10%	4	20%
3.	41-50	-	-	-	-	3	15%	-	-
4.	51-60	-	-	-	-	13	65%	14	70%

Minimum Score-0, Maximum Score-60

Pain Score	Improvement
≤30	NO
31-40	Mild
41-50	Moderate
51-60	Good

Reference:

Stratford PW Binkley JM et al. Development and initial validation of the Back pain Functional Scale. Spine.2000; 2095-2102 (Appendix-A Page:2101)

From the above table, it is observed that before treatment among 20 Out patients and 20 In patients were with pain score ≤30. After treatment, among 20 Out patients 65% have good improvement; 15%: moderate imporevement; 10% mild improvement; 10% no improvement. Among 20 In patient 70% have good improvement; 20% mild improvement; 10% no improvement.

FIGURE-26

BACK PAIN FUNCTIONAL SCALE SCORE

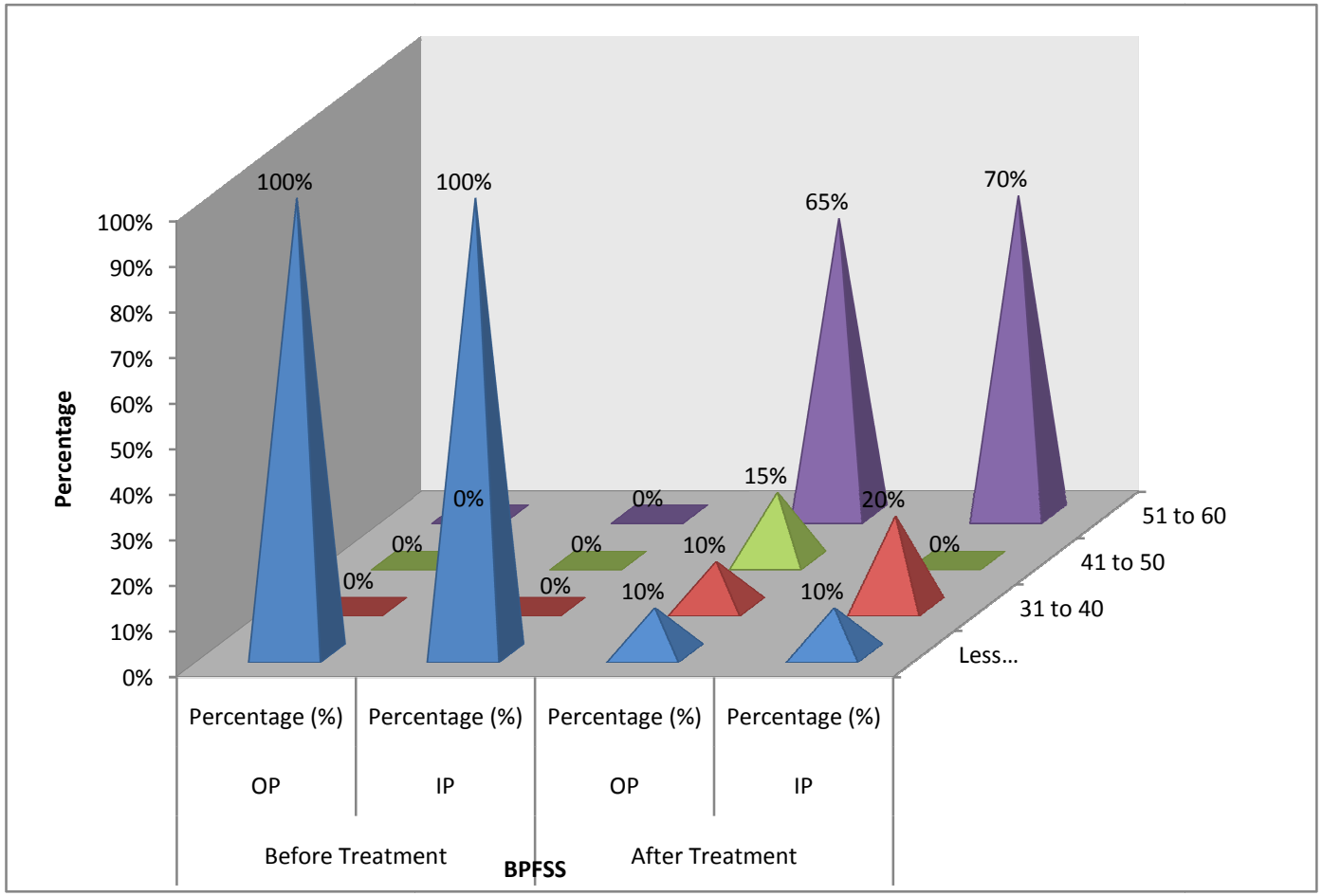


Table-26 (b) Illustrates BPFSS through Statistical Analysis

TABLE-26 (b)

BPFSS through Statistical Analysis

Sl.No	Sample	Mean ±SD		T Value	P Value	Result
		BT	AT			
1.	Out Patient	21.855±5.40	48.20±10.15	10.24	<0.0001	HS
2.	In Patient	20.10±5.71	47.10±11.72	9.26	<0.0001	HS

(n=20) List wise

BT - Before Treatment

AT-After Treatment

HS - Highly significant.

The BPFSS among out and in patients where found to be statistically highly significant at P<0.0001

27. GRADATION OF RESULTS

Table-27Illustrates Gradation of Results and its percentage.

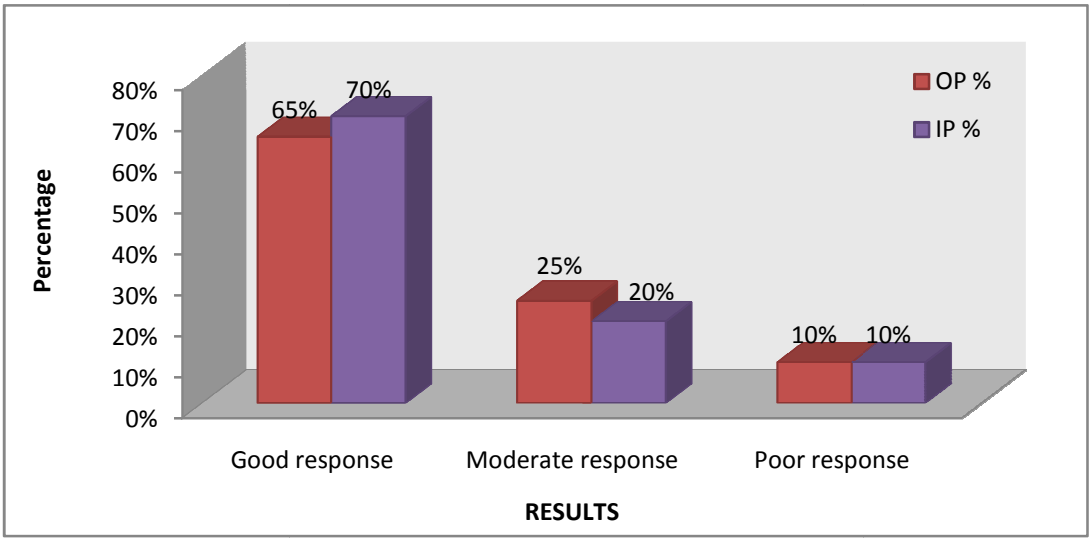
TABLE-27

GRADATION OF RESULTS

Sl. No.	**Results**	**Out Patients (OP)**		**In Patients (IP)**	
		No. of cases	**Percentage (%)**	**No. of cases**	**Percentage (%)**
1.	Good response	13	65%	14	70%
2.	Moderate response	5	25%	4	20%
3.	Poor response	2	10%	2	10%
	Total	**20**	**100%**	**20**	**100%**

FIGURE-27

GRADATION OF RESULTS



From the above table, it is observed that among 20 Out patients, 65% showed good response; 25% moderate response; 10% poor response. Among 20 In patients, 70% showed good response; 20% moderate response; 10% poor response.

TABLE-28 (a)

LABORATORY INVESTIGATION (OUT PATIENTS)

Sl. No.	Out Patient	Haematological Report														Urine Analysis					
		Before Treatment							After Treatment							Before Treatment			After Treatment		
		TC	DC			ESR		Hb % (gms)	TC	DC			ESR		Hb % (gms)	Alb.	Sug.	Dep- Epi. Cells / Puscells	Alb.	Sug.	Dep- Epi. Cells / Puscells
		Cells / cu mm	P	L	E	½ Hr.	1 Hr.		Cells / cu mm	P	L	E	½ Hr.	1 Hr.							
1.	96644	9100	60	38	3	5	28	7.0	7700	65	30	5	6	14	10.5	NIL	NIL	1-2 PUS CELLS	NIL	NIL	NAD
2.	96657	7300	62	33	5	4	20	11.1	8800	62	34	4	8	13	10.9	NIL	NIL	NAD	NIL	NIL	NAD
3.	98982	9200	64	30	6	4	9	9	6900	65	32	3	4	12	11	NIL	NIL	NAD	NIL	NIL	NAD
4.	99036	9200	60	38	2	2	4	13	9000	61	33	6	2	8	12.1	NIL	NIL	NAD	NIL	NIL	NAD
5.	100250	6600	60	34	6	9	42	10.0	8900	62	35	3	5	11	10.5	NIL	NIL	1-2PUS CELLS	NIL	NIL	NAD
6.	110477	6400	59	36	5	7	60	9.2	8300	71	24	5	7	12	12	NIL	NIL	NAD	NIL	NIL	NAD
7.	111724	8600	62	30	8	3	16	12.5	9300	63	34	3	2	4	11.3	NIL	NIL	NAD	NIL	NIL	NAD
8.	112059	9300	60	38	2	5	15	8.5	7900	61	33	6	3	6	13	NIL	NIL	NAD	NIL	NIL	NAD
9.	113104	7500	63	33	4	9	35	11.0	9400	62	33	5	3	9	11.6	NIL	NIL	NAD	NIL	NIL	NAD
10.	1131	7800	58	40	2	7	15	13	9200	67	31	2	4	13	12.7	NIL	NIL	FEW PUS CELLS	NIL	NIL	NAD
11.	5636	4800	68	29	3	10	2	11.3	9000	66	31	3	8	16	10.8	NIL	NIL	NAD	NIL	NIL	NAD
12.	3998	7200	65	30	5	3	32	10.1	8100	66	29	5	9	12	13	NIL	NIL	NAD	NIL	NIL	NAD
13.	2039	7700	60	34	6	4	8	7.6	9200	61	36	3	8	12	11.2	NIL	NIL	NAD	NIL	NIL	NAD
14.	2352	9200	60	38	2	4	4	12.2	8300	72	24	4	8	14	12.4	NIL	NIL	1-2 PUS CELLS	NIL	NIL	NAD
15.	12532	8500	58	38	4	3	7	13	9200	61	36	3	8	12	10.8	NIL	NIL	NAD	NIL	NIL	NAD
16.	12968	8800	62	36	2	4	14	11.6	8300	72	24	4	8	14	11.7	NIL	NIL	NAD	NIL	NIL	NAD
17.	15823	8800	60	33	7	7	9	6.9	8500	65	30	5	3	9	10.3	NIL	NIL	NAD	NIL	NIL	NAD
18.	15766	6700	64	34	2	9	15	12.3	8200	62	31	7	3	6	11.9	NIL	NIL	NAD	NIL	NIL	NAD
19.	15831	8900	61	36	3	8	15	9.2	8000	60	36	4	3	5	11.8	NIL	NIL	NAD	NIL	NIL	NAD
20.	23427	7500	64	36	6	9	17	8	9400	65	29	6	5	10	12.3	NIL	NIL	NAD	NIL	NIL	NAD

TABLE-28 (b)

LABORATORY INVESTIGATION (IN PATIENTS)

Sl. No.	In Patient No.	Haematological Report													Urine Analysis					
		Before Treatment							After Treatment						Before Treatment			After Treatment		
		TC	DC			ESR		Hb% (gms)	TC	DC			ESR		Hb% (gms)	Alb.	Sug.	Dep- Epi. Cells / Puscells	Alb.	Sug.	Dep- Epi. Cells / Puscells
		Cells / cu mm	P	L	E	½ Hr.	1 Hr.		Cells / cu mm	P	L	E	½ Hr.	1 Hr.							
1.	2952	7000	67	30	3	4	20	10.5	9100	71	27	2	6	11	12	NIL	NIL	1-2 Epi. Cells	NIL	NIL	NAD
2.	3046	7400	60	36	4	9	28	11.5	8300	67	29	4	4	9	11.1	NIL	NIL	Few Pus Cells	NIL	NIL	NAD
3.	342	9100	64	32	4	7	13	11.8	8100	59	35	6	4	8	12.5	NIL	NIL	NAD	NIL	NIL	NAD
4.	485	6200	63	32	5	5	25	10.4	9500	72	27	1	3	10	13	NIL	NIL	1-2 Pus Cells	NIL	NIL	NAD
5.	561	9900	80	15	5	8	70	10.5	9400	59	38	3	2	5	11.5	NIL	NIL	Few Pus Cells	NIL	NIL	NAD
6.	628	8500	65	30	5	3	10	10.4	8500	66	32	2	6	8	10.5	NIL	NIL	Few Epi. Cells	NIL	NIL	NAD
7.	633	8600	62	30	8	7	16	12.5	8900	61	36	3	4	13	10.8	NIL	NIL	NAD	NIL	NIL	NAD
8.	631	9900	80	75	5	5	70	10.2	8600	65	30	5	6	11	12.8	NIL	NIL	Few Epi. Cells	NIL	NIL	NAD
9.	630	6000	64	33	3	6	10	12.9	7000	64	35	1	5	13	10.6	NIL	NIL	NAD	NIL	NIL	NAD
10.	629	7900	63	36	2	7	90	11.8	9300	59	39	2	3	7	11.8	NIL	NIL	NAD	NIL	NIL	NAD
11.	624	6000	64	33	3	6	10	10.9	8000	63	33	4	4	8	12.4	NIL	NIL	NAD	NIL	NIL	NAD
12.	688	7000	65	37	3	5	45	10.4	9100	70	26	4	6	10	13.5	NIL	NIL	NAD	NIL	NIL	NAD
13.	719	8400	62	31	7	8	12	12.5	8800	63	33	4	3	6	12.1	NIL	NIL	NAD	NIL	NIL	NAD
14.	777	8600	62	34	4	5	15	11.0	8700	64	33	3	6	14	11.6	NIL	NIL	NAD	NIL	NIL	NAD
15.	965	8200	63	33	4	5	43	7.0	8400	63	35	2	6	12	10.5	NIL	NIL	1-2 Epi. Cells	NIL	NIL	NAD
16.	1135	7300	60	35	5	7	24	11.6	9200	65	33	2	3	6	10.9	NIL	NIL	Few Pus Cells	NIL	NIL	NAD
17.	1137	7000	63	31	3	9	19	12	9000	61	34	5	4	11	11.6	NIL	NIL	1-2 Pus Cells	NIL	NIL	NAD
18.	1136	7300	60	35	5	7	24	11.6	10000	64	32	4	7	12	12.3	NIL	NIL	Few Pus Cells	NIL	NIL	NAD
19.	1182	6700	64	32	4	2	24	12.7	9000	62	32	6	4	8	12.9	NIL	NIL	Few Pus Cells	NIL	NIL	NAD
20.	1200	6100	65	31	4	8	40	6.7	8700	60	35	5	3	7	11.5s	NIL	NIL	NAD	NIL	NIL	NAD

TABLE-29 (a)

LABORATORY INVESTIGATION (OUT PATIENTS)

Sl. No.	OP No.	Before Treatment					After Treatment				
		Blood Sugar (R)	Blood Urea	Serum cholesterol	Serum Uric acid	Serum Creatinine	Blood Sugar (R)	Blood Urea	Serum cholesterol	Serum Uric acid	Serum Creatinine
1.	96644	82	29	165	3.00	0.50	98	29	146	3.10	0.70
2.	96657	114	21	168	3.20	0.7	132	27	137	3.00	0.80
3.	98982	120	27	169	3.80	0.80	115	27	166	3.81	0.80
4.	99036	134	21	189	4.52	0.70	134	19	168	4.47	0.70
5.	100250	92	23	200	5.00	0.5	86	25	122	4.89	0.50
6.	110477	115	15	189	3.40	0.60	100	18	140	3.39	0.70
7.	111724	129	28	187	3.24	0.90	117	26	189	3.21	0.70
8.	112059	89	24	190	3.60	0.50	80	23	192	3.58	0.50
9.	113104	90	26	198	3.50	0.7	94	21	140	3.49	0.80
10.	1131	81	32	191	3.00	0.9	121	20	183	2.99	0.60
11.	5636	110	28	189	4.40	0.7	116	22	168	2.49	0.80
12.	3998	76	14	160	2.50	0.40	101	16	160	4.35	0.40
13.	2039	90	20	164	4.30	3.60	86	18	154	2.49	0.70
14.	2352	134	21	189	4.20	0.70	112	19	178	4.30	0.60
15.	12532	111	24	199	3.70	0.40	122	20	161	4.20	0.90
16.	12968	75	25	118	3.00	1.00	99	23	128	3.70	0.80
17.	15823	94	34	163	3.50	0.80	132	30	165	3.10	0.90
18.	15766	106	24	109	3.00	0.80	129	25	112	3.47	0.80
19.	15831	126	24	178	4.00	0.90	99	26	176	3.00	0.70
20	23427	98	30	189	4.00	1.00	116	27	185	4.10	0.40

TABLE-29 (b)

LABORATORY INVESTIGATION (IN PATIENTS)

Sl. No.	IP No.	Before Treatment					After Treatment				
		Blood Sugar (R)	Blood Urea	Serum cholesterol	Serum Uric acid	Serum Creatinine	Blood Sugar (R)	Blood Urea	Serum cholesterol	Serum Uric acid	Serum Creatinine
1.	2952	98	25	200	2.20	0.6	98	23	177	4.60	0.40
2.	3046	72	16	188	2.40	0.5	95	14	193	2.70	0.60
3.	342	93	28	193	4.30	0.70	114	27	124	3.10	0.50
4.	485	121	22	200	3.90	0.7	102	17	196	2.20	0.50
5.	561	120	21	162	4.00	0.5	136	24	170	3.80	0.80
6.	628	126	20	176	3.90	0.6	82	20	155	4.50	0.70
7.	633	97	35	175	3.60	0.40	127	27	149	3.50	1.00
8.	631	150	18	200	4.10	0.6	105	31	194	5.00	0.80
9.	630	76	18	200	4.30	0.6	100	32	180	3.50	0.70
10.	629	62	18	147	5.20	0.7	111	23	182	4.60	0.50
11.	624	76	18	187	4.40	0.8	125	24	197	2.60	0.80
12.	688	90	24	165	3.60	0.5	91	27	176	2.20	0.90
13.	719	109	14	192	4.50	0.80	117	15	177	4.20	0.70
14.	777	75	31	156	2.80	0.50	112	34	163	4.10	0.40
15.	965	100	25	172	3.00	0.9	132	25	174	3.80	0.80
16.	1135	132	18	130	2.20	0.6	80	21	133	3.20	0.90
17.	1137	110	15	138	4.00	0.7	120	34	140	3.40	0.60
18.	1136	132	18	130	4.60	0.6	122	26	186	4.60	0.90
19.	1182	131	19	169	3.80	0.7	101	22	158	4.70	0.60
20	1200	84	24	166	5.20	0.7	133	26	196	5.50	0.90

TABLE-30 (a)

LABORATORY AND RADIOLOGICAL INVESTIGATIONS
(OUT PATIENTS)

Sl. No.	OP No.	RA Factor (IU / ml)	ASO titre (IU / ml)	C-reative protin (mg/dl)	Radiological finding
1.	96644	6.6	90.3	1.6	Spondylotic changes L4 to L5
2.	96657	19.1	88.4	2.2	Spondylotic changes L3 to L5
3.	98982	17	79.7	2.5	Spondylotic changes L3 to L4
4.	99036	12.5	90.7	2.8	Spondylotic changes L3 to L5
5.	100250	12.3	79.8	2.6	Spondylotic changes L3 to L5
6.	110477	10.9	110.3	4.5	Spondylotic changes L3 to L5
7.	111724	14.1	90.1	5.7	Spondylotic changes L3 to L5
8.	112059	19.0	49	5.5	Spondylotic changes L4 to L5
9.	113104	18.1	64.0	1.8	Spondylotic changes L5 to S1
10.	1131	17.9	78.4	5.9	Spondylotic changes L3 to L4
11.	5636	12.6	91.2	5.2	Spondylotic changes L3to L4
12.	3998	11.7	104.0	3.1	Spondylotic changes L4 to S1
13.	2039	18.4	80.1	4.0	Spondylotic changes L2 to L4
14.	2352	18	111.0	3.9	Spondylotic changes L3 to L5
15.	12532	12.4	90.7	1.6	Spondylotic changes L5 to S1
16.	12968	17.6	88.0	2.7	Spondylotic changes L4 to L5
17.	15823	17.3	140.0	4.5	Spondylotic changes L3 to L4
18.	15766	10	93.0	5.4	Spondylotic changes L3 to L5
19.	15831	8.1	74.0	3.4	Spondylotic changes L1 to L5
20	23427	9.3	91.2	2.3	Spondylotic changes L3 to L4

Reference Range:

Rheumatoid Factor: Upto 20 IU/ml

Serum for ASO: Upto 200IU/ml

CRP: Upto 6 mg/l

TABLE-30 (b)

LABORATORY AND RADIOLOGICAL INVESTIGATIONS (IN PATIENTS)

Sl. No.	IP No.	RA Factor (IU / ml)	ASO titre (IU / ml)	C-reative protin (mg/dl)	Radiological finding
1.	2952	8.8	99.9	5.5	Spondylotic changes L5 to S1
2.	3046	8.2	65.4	3.5	Spondylotic changes L4 to L5
3.	342	7.3	89.0	2.0	Spondylotic changes L3 to L5
4.	485	7.8	30.0	4.0	Spondylotic changes L3 to L4
5.	561	5.5	89.8	5.0	Spondylotic changes L4 to L5
6.	628	3.5	61.7	2.2	Spondylotic changes L4 to L5
7.	633	4.7	95.2	5.3	Spondylotic changes L4 to S1
8.	631	6.8	88.8	1.4	Spondylotic changes L4 to L5
9.	630	8.7	75.5	2.1	Spondylotic changes L3 to L5
10.	629	5.3	60.0	5.5	Spondylotic changes L3 to L4
11.	624	7.4	10.0	3.8	Spondylotic changes L4 to L5
12.	688	11.4	60.7	3.6	Spondylotic changes L3 to L5
13.	719	15.7	19.0	5.8	Spondylotic changes L2 to L5
14.	777	1.30	80.6	3.7	Spondylotic changes L2 to L5
15.	965	7.0	70.5	4.5	Spondylotic changes L3 to L4
16.	1135	9.2	100.1	2.5	Spondylotic changes L3 to L5
17.	1137	5.6	79.9	6.9	Spondylotic changes L3 to L4
18.	1136	14.2	85.2	3.2	Spondylotic changes L3 to L5
19.	1182	6.5	50.8	3.5	Spondylotic changes L3 to L4
20	1200	4.5	92.4	5.2	Spondylotic changes L3 to L5

Reference range:

Rheumatoid Factor: Upto 20IU/ml

Serum for ASO: Upto 200 IU/ml

CRP: Upto 6 mg/L

TABLE-31 (a)

BACK PAIN FUNCTIONAL SCALE SCOREVALUES (OUT PATIENTS)

Sl. No.	OP No.	Pain score	
		Before Treatment	After Treatment
1.	96644	24	56
2.	96657	17	47
3.	98982	15	24
4.	99036	10	27
5.	100250	20	43
6.	110477	26	51
7.	111724	23	53
8.	112059	16	39
9.	113104	13	33
10.	1131	23	52
11.	5636	30	52
12.	3998	27	55
13.	2039	26	57
14.	2352	28	51
15.	12532	22	55
16.	12968	25	53
17.	15823	21	59
18.	15766	19	45
19.	15831	27	54
20	23427	25	58

Interpretation:

≤30 : No improvement / High disease activity

31-40 : Mild improvement

41-50 : Moderate improvement

51-60 : Good improvement

TABLE-31 (b)

BACK PAIN FUNCTIONAL SCALE SCORE VALUES (IN PATIENTS)

Sl. No.	IP No.	Pain score	
		Before Treatment	After Treatment
1.	2952	20	50
2.	3046	15	35
3.	342	27	58
4.	485	18	52
5.	561	16	57
6.	628	24	50
7.	633	26	53
8.	631	17	15
9.	630	19	28
10.	629	23	51
11.	624	28	54
12.	688	30	59
13.	719	12	55
14.	777	21	33
15.	965	22	56
16.	1135	12	38
17.	1137	17	53
18.	1136	13	54
19.	1182	28	51
20	1200	14	40

Interpretation:

≤30 : No improvement / High disease activity

31-40 : Mild improvement

41-50 : Moderate improvement

51-60 : Good improvement

TABLE-32 (a)

CASE SUMMARY (OUT PATIENTS)

Sl. No.	OP No.	Name	Age / Sex	Occupation	Duration of illness	Treatment starting date	End of treatment	Total Days	Results
1.	96644	Kala	57/F	House Wife	1 ½ Years	3.11.17	2.12.17	30	Good
2.	96657	Paasha	39/M	Business	4 Years	3.11.17	2.12.17	30	Fair
3.	98982	Kathiresan	48/M	Agricultural labour	10 Months	10.11.17	9.12.17	30	Poor
4.	99036	Manthiram	35/M	Coolie	11 Months	10.11.17	9.12.17	30	Poor
5.	100250	Isakiammal	58/F	House wife	6 Months	14.11.17	13.12.17	30	Fair
6.	110477	Velammal	37/F	House wife	5 Years	14.12.17	12.1.18	30	Fair
7.	111724	Siva Ganam	58/F	House wife	3 Years	18.12.17	16.1.18	30	Poor
8.	112059	Murukesan	59/M	Watchman	2 ½ Years	19.12.17	17.1.18	30	Fair
9.	113104	Nisha	38/F	Tailor	2 Years	22.12.17	20.1.18	30	Fair
10.	1131	Guru Dhas	60/M	Watchman	2 Years	3.1.18	1.2.18	30	Good
11.	5636	Arumuga Samy	41/M	Agricultural labour	2 Years	10.1.18	8.2.18	30	Good
12.	3998	Thankam	43/F	Coolie	1 Year	10.1.18	8.2.18	30	Good
13.	2039	Thanka Raj	56/M	Driver	7 Years	12.1.18	10.2.18	30	Good
14.	2352	Seyyed Ali	43/M	Tailor	3 Years	24.1.18	22.2.18	30	Good
15.	12532	Abdhul Kaadhar	40/M	Agricuitural labour	3 years	6.2.18	7.3.18	30	Good
16.	12968	Maari Muthu	38/M	Business	6 Years	7.2.18	8.3.18	30	Good
17.	15823	Kumar	39/M	Business	4 Months	1.3.18	30.3.18	30	Good
18.	15766	Sankar	31/M	Loadman	3 Years	1.3.18	30.3.18	30	Good
19.	15831	Jegadeeshwari	40/F	Coolie	8 Months	1.3.18	30.3.18	30	Good
20.	23427	Ayisha	53/F	Tailor	4 Years	9.3.18	7.4.18	30	Good

TABLE-32 (b)

CASE SUMMARY (IN PATIENTS)

Sl. No.	IP No.	Name	Age / Sex	Occupation	Duration of illness	Treatment starting date	End of treatment	Total Days		Total Days	Results
								IP	OP		
1.	2952	Kandasamy	37/M	Coolie	3 Years	3.11.17	2.12.17	30	-	30	Good
2.	3046	Lakshmi	58/F	House Wife	2 Years	14.11.17	28.11.17	15	15	30	Fair
3.	342	Sudalai	50/M	Agricultural labour	3 Years	8.2.18	14.2.18	7	23	30	Fair
4.	485	Sharmila	37/F	Tailor	6 Months	22.2.18	12.3.18	19	11	30	Good
5.	561	Ranjitham	60/F	House Wife	7 Months	1.3.18	12.3.18	12	18	30	Good
6.	628	Chella Thurai	60/M	Business	2 Years	8.3.18	19.3.18	12	18	30	Fair
7.	633	Uma Chanthiran	60/M	Loadman	8 Months	8.3.18	14.3.18	7	23	30	Poor
8.	631	Nata Rajan	60/M	Driver	6 Years	8.3.18	14.3.18	7	23	30	Poor
9.	630	Venkatesh	38/M	Business	7 Years	8.3.18	19.3.18	12	18	30	Fair
10.	629	Ravinthran	60/M	Driver	3 Years	8.3.18	6.4.18	30	-	30	Good
11.	624	Sankara Pandian	60/M	Business	1 Year	8.3.18	6.4.18	30	-	30	Good
12.	688	Isakkiammal	48/F	House Wife	4 Years	13.3.18	29.3.18	17	13	30	Good
13.	719	Hariharan	46/M	Agricultural labour	2 Years	15.3.18	29.3.18	15	15	30	Fair
14.	777	Krishnasamy	43/M	Business	3 ½ Years	21.3.18	18.4.18	29	1	30	Good
15.	965	Parvathi	45/F	Agricultural labour	9 Months	10.4.18	9.5.18	30	-	30	Good
16.	1135	Esakki	39/M	Agricultural labour	2 Years	26.4.18	17.5.18	22	8	30	Good
17.	1137	Suseela	47/F	House Wife	1 Year	26.4.18	25.4.18	30	-	30	Good
18.	1136	Velappan	49/M	Tailor	2 Years	26.4.18	25.4.18	30	-	30	Good
19.	1182	Suresh kumar	40/M	Coolie	2 Months	1.5.18	30.5.18	30	-	30	Good
20.	1200	Indhira	50/F	House Wife	11 Months	3.5.18	1.6.18	30	-	30	Good

CHAPTER-VI

DISCUSSION

Thandaga Vatham has described by Yugi Munivar in ***'Yugi Vaidhiya Chinthamani-800'*** is nearly correlated in modern medicine is Lumbar Spondylosis. In this clinical trial study totally 40 patients were selected, 20 were treated as Out patients and 20 were treated as In patients with clinical trial drug ***'VAEPPAM PATTAI KUDINEER'*** 50ml twice a day. The most important clinical features of Thandaga Vatham is pain in low back area, stiffness, restricted movements, tenderness, numbness and radiating pain.The diagnosis was made by Siddha and modern diagnostic tools.

Institutional ethiclal committee clearance was obtained for this study with IEC No.GSMC/3-IEC/2016-I-3/20.07.2016.

To evaluate the standardization of the trial drug, it is authenticated through visual inspection and organoleptic characters. To ensure safety is made through vivo and vitro studies.

Professor, Associate Professor and Lecturers of the Department of Pothu Maruthuvam had supervised the entire clinical study, its observation and results.

The observed results were discussed below:

1. Incidence with Age Distribution:

The disease was found to be higher in the age group of 41-50 in both OP and IP (OP-40% & IP-65%)

2. Incidence with Sex Distribution:

- 60% of the Out paitents were males and 40% were females.
- 65% of the In patients were males and 35% were females.

3. Distribution according to Kaalam:

Greater part of the cases belonged to Pitha Kaalam which is commonly the period of degeneration (OP-95% & IP-100%).

4. Distribution according to Paruva Kaalam:

High incidence of the disease was in Munpani Kaalam with 45% in OP and Pinpani Kaalam with 60% in IP.

5. Incidence with Thinai:

Most of the cases were reported from Marutham (OP-100% & IP-70%).

6. Incidence with reference to Constitution of the Body:

Vatha Thegi were much affected (OP-80% & IP-75%)

7. Incidence with reference to Gunam:

All cases had Rajo Gunam.

8. Incidence with reference to Religion:

The highest incidence was found to be among Hindus (OP-80% & IP 95%)

9. Incidence with reference to Socio-Economic Status:

In this clinical study most of the patients were from low income class with 80% in IP and also from low income class with 70% in OP.

10. Incidence with reference to Food Habit:

Most of the patients belonged to non-vegeterian (OP-90% & IP-70%).

11. Incidence with reference to Family History:

Most of the patients don't have family history related to this disease (OP-85% & IP-85%).

12. Incidence with reference to Occupation:

Most of the patients strained themselves as heavy workers, lifting heavy weight, travelling a long distance and sitting for a long period of time. These may be the reasons to develop Thandaga Vatham.

13. Incidence with reference to Aetiological Factors:

Age, obesity and occupation were the main precipitating factors in majority of cases.

14. Incidence with reference to Mode of Onset:

Most of the patients were observed in chronic state (OP-100% & IP-100%).

15. Incidence with Duration of Illness:

Majority of the cases were observed above 12 months of duration (OP-70% & IP-60%).

16. Incidence with Clinical Manifestation:

100% of both OP & IP had low back pain and exacerbation of pain on movements. Radiating pain to lower limbs, restricted movements, stiffness, tenderness and numbness were present in variable number among the patients under study.

17. Incidence with reference to Kanmenthiriyam:

- Kaal was affected among 85% of OP & 100% of IP.

18. Incidence with reference to Gnanendrium:

- Mei (Local heat) was affected among 25% of OP and 35% of IP.

19. Incidence with reference to Kosam:

- Vinganamaya Kosam (Restriction of movements, low back pain) was affected in all cases.
- Annamaya Kosam (Anorexia)was affected among 30% of OP & 25% of IP.

20. Condition of Mukkutram:

a). Disturbance in Vatham:

- Koorman was affected among 10% of OP.
- Kirukaran (Secretion of saliva) was affected among 10% of OP and 25% of IP.

- Viyaanan (Movements, nervous functions and sensation), Samaanan (Regulates the digestion and controls all the other vayus) and Devathathan (Laziness) were affected in all cases.
- Abaanan (Constipation) was affected among 35% of OP and 25% of IP.

b). Disturbance in Pitham:

- Sathagam (Wilful activities) was affected in all cases.
- Analagam (Digestion) was affected among 30% of OP and 25% of IP.
- Ranjagam (Nutrition to blood) was affected among 25% of OP and 10% of IP.

c). Disturbance in Kapham:

- Santhigam (Integrity of joints) was affected in all cases.
- Klethagam (Lubrication of food) was affected among 30% of OP and 25% of IP.

21. Incidence with reference to Udal Thathukkal:

Saaram, Kozhuppu, Enbu were affected in all cases. Senner was affected among25% of OP and 10% of IP. Disturbance in Saaram produce symptoms like lethargy and mental depression. Disturbance in senner was associated with Anemia. Disturbance in Kozhuppu, Enbu produce restricted movements, reduced intervertebral disc space, extra osteophyticchanges and degenerative spondylotic changes in Lumbar Vertebrae.

22. Incidence with reference to Envagai Thervugal:

- In this study all cases had thontha naadi with high incidence of Vatha Pitham (OP-55% & IP-60%).
- Sparisam was affected among 25% of OP and 30% of IP.
- Vizhi was affected among 35% of OP & 10% of IP.
- Malam was affected among 35% of OP & 25% of IP.

23. Incidence with reference to Neer Kuri:

- Niram was affected among 30% of OP & 35% of IP.

24. Incidence with reference to Neikuri:

Majority of cases showed the neikuri as spreading like snake, when the oil is dropped into the urine indicating the predominance of Vatha neer (OP-90% & IP-85%).

25. Incidence with reference to Radiological Studies:

From the X-Ray of Lumbar spine (AP & Lateral view) all the cases had degenerative spondylotic changes. Reduced intervertebral disc space found among 10% of OP and 15% of IP. After treatment no changes is noted in X-Rays.

26 (a) Assessment of Outcome - Back pain functional scale score.

After treatment65% of OP and 70% of IP had good improvement. 25% of OP and 20% of IP had moderate improvement.10% of OP and IP had mild improvement.

27. Incidence with reference to results:

- 65% of OP and 70% of IP had good response.
- 25% of OP and 20% of IP had moderate response.
- 10% of both OP & IP had poor response.
- It was found that the end of result showed good clinical improvement in grade with reduction of low back pain, numbness, stiffness, radiating pain, tenderness and restricted movements.

The statistical analysis of the observational parameters clearly indicates that Vaeppam Pattai Kudineer is highly siginificant in the treatment of Thandaga Vatham.

Biochemical analysis of ***VAEPPAM PATTAI KUDINEER*** showed the presence of sulphate, starch, ferrous iron, amino acid, unsaturated compound and reducing sugar.

Acute oral toxicity of ***VAEPPAM PATTAI KUDINEER*** given to albino mice did not produce toxicities.

Thus ***VAEPPAM PATTAI KUDINEER*** by virtue of its actions mentioned previously help in reducing the cardinal signs of lumbar spondylosis and prevents further degeneration.

CHAPTER-VII

SUMMARY

An open labelled randomized clinical study on **"THANDAGA VATHAM"** with reference to its aetiology, pathogenesis, clinical features, diagnosis, investigations and treatment were conducted at Department of Pothu Maruthuvam, Government Siddha Medical CollegeHospital, Palayamkottai.

This clinical study of Thandaga Vatham is done on the basis of reference in **Yugi Vaidhya Chinthamani-800,** which is correlated with Lumbar Spondylosis.

The trial drug chosen for the clinical study is **'VAEPPAM PATTAI KUDINEER'**. Dosage 50ml twice daily after food for 30 days ***(Ref: Gunapadam Mooligai Vagupu, Page No.859).***

A number of literatures were collected regarding Siddha as well as modern system of medicine.

For this study, out of 40 patients, 20 patients were diagnosed clinically and admitted in the In patients ward and treated with trial medicines. Another 20 as Out patients.

The selection and management of patients during admission and after treatment is carried out under the supervision of Professor, Associate Professor, Lecturers of Department of Pothu Maruthuvam.

A log book and a case sheet proformais prepared with particulars focussed on Siddha and Modern clinical parameters.

Separate case sheets were maintained for each patient in In patient ward and their vital signs and symptoms were monitored and recorded daily. The patient treated with the trial drug ***VAEPPAM PATTAI KUDINEER*** twice a day daily.

In case of Out patients, the trial drug this made into packets of 7 grms. 4 such packets are given and the method of preparing infusion is instructed. They have

visited the hospital once in two days. At each visit clinical assessment and prognosis were noted.

Routine blood examinations, urine analysis, specific investigations and radiological investigations were done by scientific methods and were considered for diagnosis and progress of the patients.

Siddha diagnosis is achieved with the help of Envagai Thervugal and Ezhu Udal Thathukkal.

Since Thandaga Vatham is a chronic disease, it requires treatement for minimum thirty days to minimize severe pain, tenderness, swelling and stiffness further the patient is advised to follow up the treatment in Out patients department.

From this study the following datas are clear that the disease was more common in males then femals. The disease has increased incidence among individuals with more physical activity, higher BMI scores. Despite marked variability within the population, men appear to have more significant degenerative changes than women. Maximum incidence was in Pitha Kaalam. Clinically marked reduction in the symptoms along with increase sense of well being, **improvement in the grade of cardinal signs and range of motion,** decrease in the **"BACK PAIN FUNCTIONAL ASSESSMENT SCORE"** was noted.

The patients were observed for a period of 3 months during and after the course of treatment. No signs of complications were reported. Clinically no toxic effects were noticed during the treatment period. The Pharmacological evaluation and biochemical analysis of **VAEPPAM PATTAI KUDINEER** were also carried out.

Results of this clinical trial study statistically proved significant.

CHAPTER-VIII

CONCLUSION

Thandaga Vatham mentioned in ***Yugi Vaidhya Chinthamani-800*** which is correlated with the clinical conditions as Lumbar spondylosis is a greatest hazard to the world. The people suffering from lumbar spondylosis goes on increasing day by day even at the age of 20. This is a wear and tear mechanism that people could not stop to take relaxment in their time clock until some mechanical stress and pain happens. So a treatment is essential for them inspite of their work to cure the disease.

The disease **'*Thandaga Vatham*'** is treated with ***Vaeppam Pattai Kudineer*** and is well analysed under Siddha and modern parameters. The cases were thoroughly examined with clinical and biochemical report.

Of the total 40 patients, 67.5% showed good response; 22.5% showed moderate response; 10% showed poor response. Thus, I conclude that mankind has got a better remedy. I hope this trial drug **'*VAEPPAM PATTAI KUDINEER*'** would add a feather to the glory of Siddha system and brings it to a new leap on forth coming research.

வேப்பம்பட்டை குடிநீரில் சேரும் சரக்குகள்

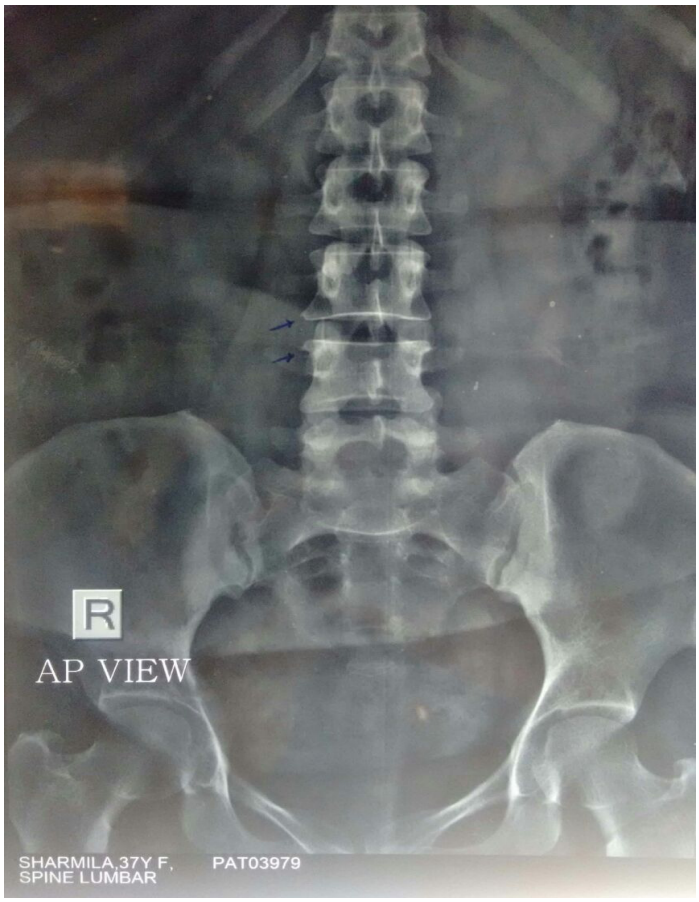
வேப்பம்பட்டை

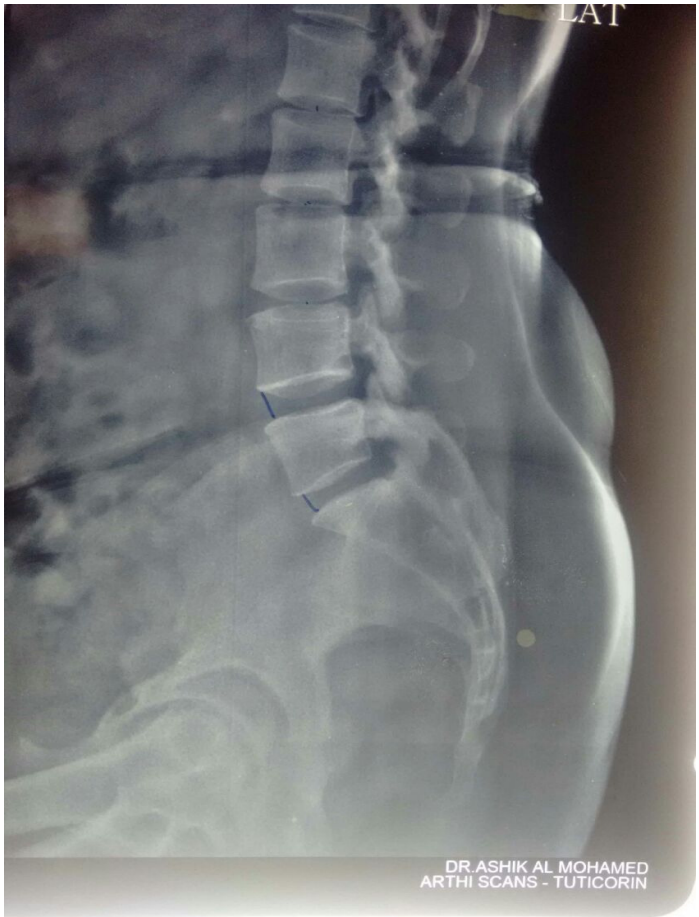
திப்பிலி

வேப்பம்பட்டை குடிநீர்

BEFORE TREATMENT

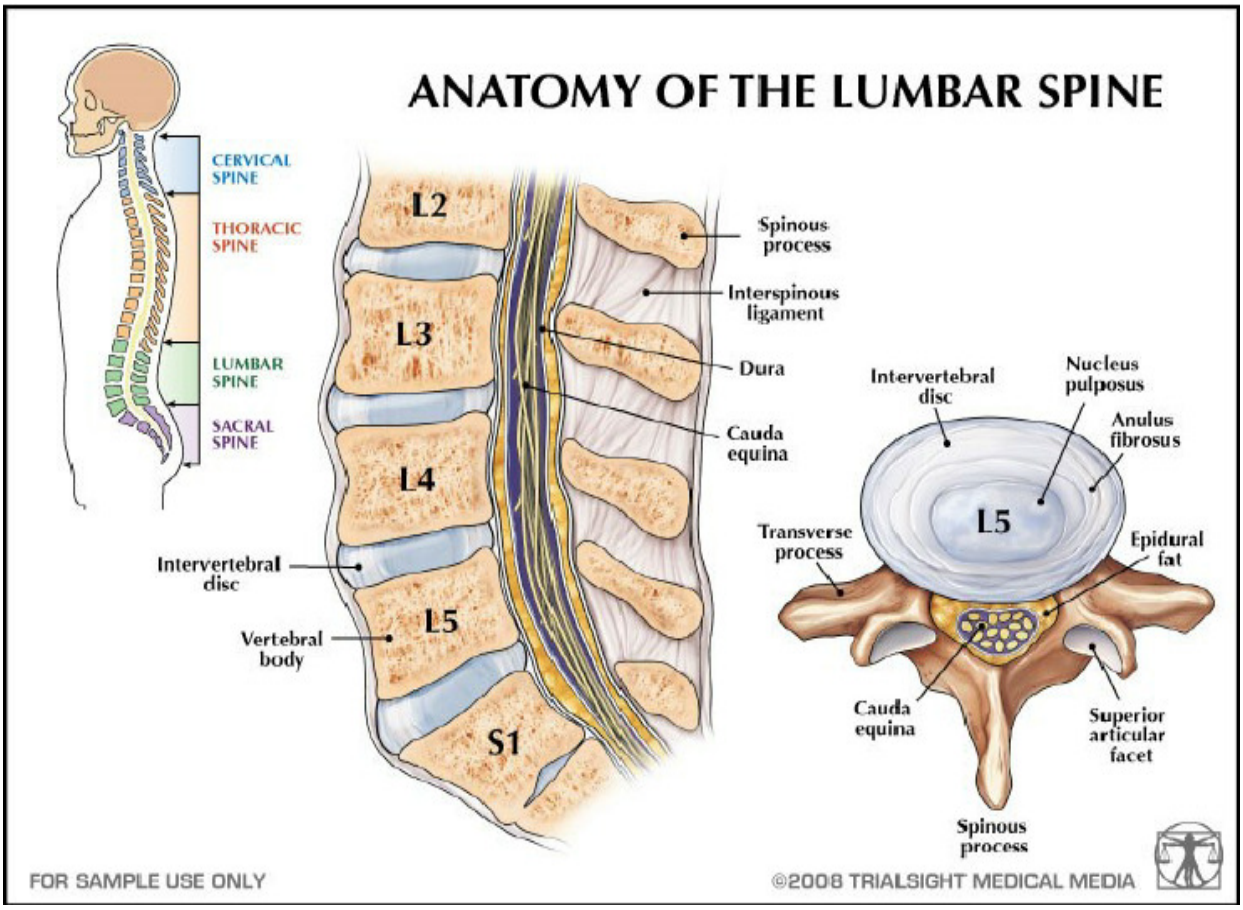
Name : SHARMILA **IP NO : 485** **Age/Sex : 37Y/F**





AFTER TREATMENT

Name : SHARMILA **IP NO : 485** **Age/Sex : 38Y/F**


ANATOMY OF THE LUMBAR SPINE
CERVICAL SPINE
THORACIC SPINE
LUMBAR SPINE
SACRAL SPINE
L2
L3
L4
L5
S1
Spinous process
Interspinous ligament
Dura
Cauda equina
Intervertebral disc
Vertebral body
Intervertebral disc
Nucleus pulposus
Anulus fibrosus
L5
Transverse process
Epidural fat
Cauda equina
Superior articular facet
Spinous process
FOR SAMPLE USE ONLY
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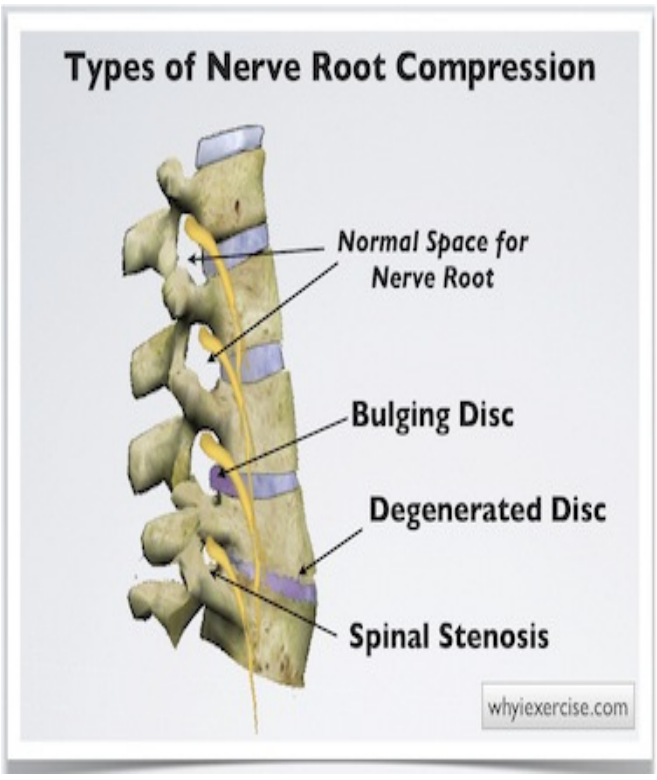
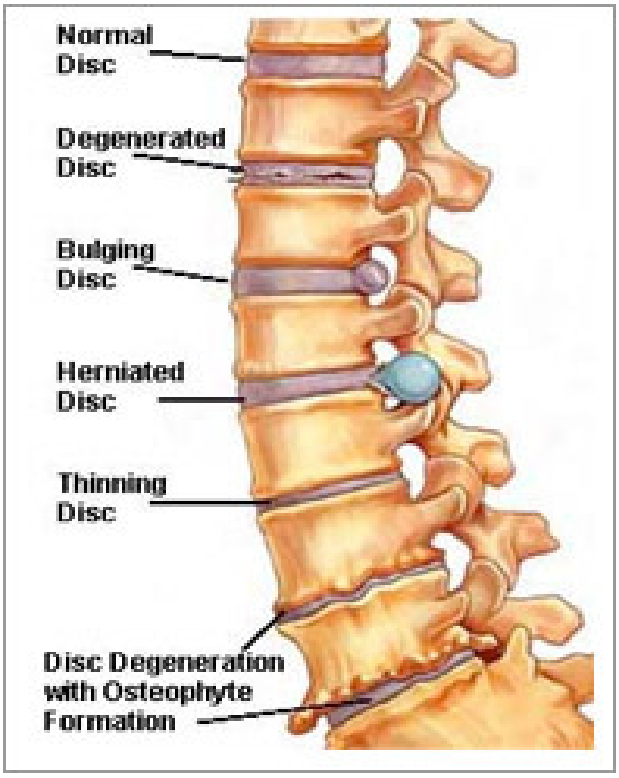

Types of Nerve Root Compression
Normal Space for Nerve Root
Bulging Disc
Degenerated Disc
Spinal Stenosis
whyiexercise.com


Normal Disc
Degenerated Disc
Bulging Disc
Herniated Disc
Thinning Disc
Disc Degeneration with Osteophyte Formation

ANNEXURE – I

PREPARATION AND PROPERTIES OF TRIAL MEDICINE

வேப்பம் பட்டைக் குடிநீர்

(Reference: Gunapadam Mooligai Part-I, Page No:859)

வேப்பம் பட்டை 4 கிராம், திப்பிலி 8 கிராம் சேர்ந்த குடிநீரை இடுப்பு வாதம், கீல்வாதத்திற்கு வழங்கிவர, நற்பயன் கொடுக்கும்.

1.	Drug Name	:	Vaeppam Pattai
	Botanical Name	:	Azadirachta indica
	Family	:	Meliaceae
	Part used	:	Bark
	Phyto chemicals	:	Nimbidal, Nimbidin, Gedunin
	Action	:	Anti-inflammatory, Anti-arthritic, Anti-pyretic, Analgesic, Immuno-stimulant, Astringent, Demulcent.
	Therapeutic uses	:	Vatha diseases, hyperdipsia, leprosy, skin diseases, eczema, leucoderma, pruritis, intermittent and malarial fevers, wounds, ulcers, burning sensation, tumour, anorexia, vomiting, inflammation, syphilis.
2.	Drug Name	:	Thippili
	Botanical Name	:	Piper longum
	Family	:	Piperaceae
	Part used	:	Dried spike
	Phyto chemicals	:	Resin, Volatile, Starch, Fatty acid, Piperine.
	Actions	:	Analgesic, Anti-inflammatory, Sedative, Tonic, Carminative, Vermifuge, Emmenagogue.
	Therapeutic uses	:	Bronchial asthma, insomnia, jaundice, viral hepatitis, rheumatism, cough, bronchitis, muscular pains, inflammation, dysentry, leprosy.
	Dose	:	50 ml – twice a day
	Duration	:	30 days

METHOD OF PREPARATION:

The purified drug is coarsely pounded. For the preparation of decoction 25 grams of the powder is boiled and made kasayam for dispensing to patients.

வேப்பம் பட்டை:

சுவை	:	கைப்பு, சிறு துவர்ப்பு
தன்மை	:	வெப்பம்
பிரிவு	:	கார்ப்பு

திப்பிலி:

சுவை	:	இனிப்பு
தன்மை	:	வெப்பம்
பிரிவு	:	இனிப்பு

PURIFICATION OF DRUGS:

Vaeppam Pattai :

Removes the adulterant and make it dried on the shade light.

Thippili :

Soak in lime juice and make it dry.

ANNEXURE- II

BIO CHEMICAL ANALYSIS OF "VAEPPAM PATTAI KUDINEER"

Preparation of the extract:

5gms of the drug was weighed accurately and placed in a 250 ml clean beaker then 50 ml of distilled water is added and dissolved well. Then it is boiled well for above 10 minutes. It is cooled and filtered in a 100 ml volumetric flask and then it is made to 100 ml with distilled water this fluid is taken for analysis.

QUALITATIVE ANALYSIS

S. NO.	EXPERIMENTS	OBSERVATION	INFERENCE
1.	**Test For Calcium:** 2ml of the above prepared extract taken in a clean test tube. To this add 2ml of 4% Ammonium oxalate solution.	No white precipitate is formed.	Absence of Calcium.
2.	**Test For Sulphate:** 2ml of the extract is added to 5% Barium Chloride Solution.	A white precipitate is formed.	Indicates the presence of sulphate.
3.	**Test For Chloride:** The extract is treated with silver nitrate solution.	No white precipitate is formed.	Absence of chloride.
4.	**Test For Carbonate:** The substance is treated with concentrated Hcl.	No brisk effervescence is formed.	Absence of carbonate.
5.	**Test For Starch:** The extract is added with weak iodine solution.	Blue colour is formed.	Indicates the presence of starch.
6.	**Test For Ferric Iron:** The extract is acidified with Glacial acetic acid and potassium ferro cyanide.	No Blue colour is formed.	Absence of ferric iron.

7.	**Test For Ferrous Iron:** The extract is treated with concentrated nitric acid and Ammonium thiocyanate solution.	Blood red colour is formed.	Indicates the presence of ferrous iron.
8.	**Test For Phosphate:** The extract is treated with Ammonium Molybdate and concentrated nitric acid**.**	No yellow precipitate is formed	Absence of phosphate
9.	**Test For Albumin:** The extract is treated with Esbach's reagent**.**	No yellow precipitate is formed.	Absence of Albumin.
10.	**Test For Tannic Acid:** The extract is treated with ferric chloride.	No blue black precipitate is formed.	Absence of Tannic acid.
11.	**Test For Unsaturation:** Potassium permanganate solution is added to the extract.	It gets decolorized.	Indicates the presence of unsaturated compound.
12.	**Test For The Reducing Sugar:** 5ml Of Benedict's qualitative solution is taken in a test tube and allowed to boil for 2 minutes and add 8 to 10 drops of the extract and again boil it for 2 minutes	Colour change occurs.	Indicates the presence of reducing Sugar.
13.	**Test For Amino Acid:** One or two drops of the extract is placed on a filter paper and dried well. After drying, 1% Ninhydrin is sprayed over the same and dried it Well.	Violet colour is formed.	Indicates the presence of Amino acid.
14.	**Test For Zinc:** The extract is treated with Potassium Ferro cyanide.	No white precipitate is formed.	Absence of Zinc.

INFERENCE

Indicates the presence of sulphate, starch, ferrous iron, amino acid, unsaturated compound and reducing sugar.

ANNEXURE – III

PHARMACOLOGICAL ANALYSIS

ANALGESIC ACTIVITY OF SIDDHA FORMULATION OF VAEPPAM PATTAI KUDINEER

ANALGESIC ACTIVITY

Analgesic activity of siddha formulation Vaeppam Pattai Kudineer was evaluated by acetic acid induced writhing reflux in mice. Painful reaction in animals may be produced by the chemicals such as phenylquinone, bradykinin etc. Like that, acetic acid pain reaction which is characterized as a writhing response. Construction of abdomen, turning of trunk (twist) and extension of hind legs are taken as reaction to chemically induced pain. Analgesics (both narcotic and non-narcotic) inhibit writhing response.

REQUIREMENTS:

Animal : Swiss albino mice (20-25g) either sex

Drugs and chemicals : Diclofenac sodium (standard),

Acetic acid (1%v/v), Vaeppam Pattai Kudineer

METHOD:

TREATMENT PROTOCOL

Group-1 Treated as normal control received 10ml/kg of normal saline through orally.

Group-2 Treated as Standard control received 10mg/kg of diclofenac sodium through Intraperitonealy.

Group-3 Treated as treatment control received 100mg/kg of Vaeppam Pattai Kudineer administered through orally.

Group-4 Treated as treatment control received 200mg/kg of Vaeppam Pattai Kudineer administered through orally.

Siddha formulation Vaeppam Pattai Kudineer was administered one hour prior to the acetic acid administration. Note the onset on writhing. Record the numbers of abdominal contractions, trunk twist and extension of hind limbs as well as the number of animals showing such response during a period of 10 minutes were noted.

STATISTICS:

Data are expressed as mean ± SEM; data analyzed by one way ANOVA followed by Newman's keul's multiple range tests to determine the significance of the difference between the control group and rats treated with the extracts.

* Values were considered significant at $P< 0.01$.

TABLE No.1

ANALGESIC ACTIVITY OF VAEPPAM PATTAI KUDINEER BY ACETIC ACID INDUCED WRITHING REFLUX IN MICE

Treatment	Dose (mg/kg)	No. of writhing	% reduction in reaction time
Group I Normal saline	Inject 1%v/v acetic acid 1ml/100g of body weight	48.9±2.65	-
Group II Std	10mg/kg I.P.Diclofenac sodium	15.6±0.76	68.09%**
Group III Vaeppam Pattai Kudineer	100mg/kg Administered through orally.	22.6±1.48	53.78%**
Group IV Vaeppam Pattai Kudineer	200mg/kg Administered through orally	20.3±1.20	58.48%**

Values are expressed as mean±SEM

Values were find out by using one-way ANOVA followed by Newman's keuls multiple range tests.

** Values were considered significant at P< 0.01.

RESULTS:

The table values show that analgesic activity of Vaeppam Pattai Kudineer by acetic acid induced writhing reflex. The results reveals that both dose of Vaeppam Pattai Kudineer possess significant analgesic activity at p<0.01.

ANTI-INFLAMMATORY ACTIVITY OF SIDDHA FORMULATION

VAEPPAM PATTAI KUDINEER

The anti-inflammatory activities of siddha formulation Vaeppam Pattai Kudineer at a dose of 100 and 200mg/kg were evaluated using carrageenan-induced paw edema method. The inflammation was readily produced in the form of edema with the help of irritant such as carrageenan. Carrageenan is a sulphated polysaccharide obtained from sea weed (Rhodophyceae) and when injected cause the release of prostaglandins by the way it produces inflammation and edema.

REQUIREMENTS:

Animal	:	Albino rat (180-200 g)
Drugs and chemicals	:	Carrageenan (1%w/v), Diclofenac sodium (standard),
		Carboxy methyl cellulose (1%w/v),
		Digital plethysmo meter. U G O Basile (Italy)
Test compounds	:	Siddha formulation Vaeppam Pattai Kudineer

METHOD:

Anti-inflammatory activity was performed by the following procedure of Bhandri et al(1) The animals were divided into 4 groups each having six animals. A freshly prepared suspension of carrageenan (1% w/v , 0.1 ml) was injected to the planter region of left hind paw of each rat. One group was kept as control and the animals of the other groups were pretreated with the siddha formulation Vaeppam Pattai Kudineer test Compounds dissolved with 2 ml sterile water given through orally 30 min before the carrageenan treatment. The paw volumes of the test compounds, standard and control groups were measured at 60,240,360 minutes of carrageenan treatment with the help of Digital plethysmometer (Ugo basile, Italy). Mean increase in paw volume was measured and the percentage of inhibition was calculated.

% Anti-inflammatory activity = (Vc-Vt / Vc) x 100

Where, ***Vt***-mean increase in paw volume in rats treated with test compounds,

Vc-mean increase in paw volume in control group of rats.

TABLE No.1

ANTI-INFLAMMATORY ACTIVITY OF SIDDHA FORMULATION VAEPPAM PATTAI KUDINEER

Treatment	**Dose (mg/kg)**	**Paw volume(ml) as measured by mercury displacement at 6 hour**	**Percentage inhibition of paw edema**
Group I Normal saline	10ml/kg orally	5.58±0.93	-
Group II Std	10mg/kg Diclofenac sodium I.P.	1.74±0.41	68.81%*a
Group III Vaeppam Pattai Kudineer	100mg/kg.Orally.	2.08±0.52	62.72%*a
Group IV Vaeppam Pattai Kudineer	200mg/kg.Orally.	1.97±0.45	64.69%*a

* Data are expressed as Mean ± S.E.M.

* Data were analyzed by one way ANOVA followed by Newman's keul's multiple range tests, to determine the significance of the difference between the control group and rats treated with the test compounds.

* Data values were significantly different from normal control at P< 0.01.

Results:

Anti- inflammatory activity

Both doses of siddha formulation Vaeppam Pattai Kudineer at 100mg/kg and 200mg/kg were tested for their Anti- inflammatory activity by using carrageenan Induced rat paw edema method and the results are tabulated in table no 1. The results reveals that both doses of siddha formulation Vaeppam Pattai Kudineer at 100mg/kg and 200mg/kg doses possesses significant Anti- inflammatory activity when compared to control group at $p<0.01$.

ANNEXURE – IV
ACUTE TOXICITY STUDY

Acute toxicity study of Vaeppam Pattai Kudineer :

Determination of acute oral toxicity is usually the initial screening step in the assessment and evaluation of the toxic characteristics of all compounds. The types of toxicity tests which are routinely performed by pharmaceutical manufacturers in the investigation of a new drug involve acute, sub-acute and chronic toxicity. Acute toxicity is involved in estimation of LD_{50} (the dose which has proved to be lethal (causing death) to 50% of the tested group of animals)

(Shetty Akhila, *et al.,* 2007).(1)

Method: Acute oral toxicity of Vaeppam pattai kudineer is carried out as per the guidelines Organization of Economic Co-operation and Development (OECD) -423 guidelines after the animal ethical clearance from Institutional Animal Ethics Committee.

The albino mice are fasted over night and provided only water, after which the **Vaeppam Pattai kudineer** is administered by gastric intubations to the relevant group of animals orally at the dose of 50 $mg.kg^{-1}$ body weight in Tween-80. The animals are then observed for 14 days and maintained with normal food. A mortality rate of 2 or 3 animals in 14 days is recorded and the dose is said to be toxic dose. But when mortality of one animal is observed, then the same dose is repeated again for confirmation. However, if mortality is not observed, the procedure is repeated for further higher doses such as 300 and 2,000 $mg.kg^{-1}$ body weight. Toxic symptoms are observed for 72 hrs including behavioral changes, locomotion, convulsions and mortality (Shah Ayub, 1997, Bürger, 2005).(2,3).

Cage Side Observations:

Observations include changes in skin and fur, eyes and mucous membranes, and also respiratory, circulatory, autonomic and central nervous systems, and somatomotor activity and behavior pattern. Special attention is directed for the observation of tremors, convulsions, salivation, diarrhea, lethargy, sleep and coma.

Body Weight, Food and Water Intake:

Body weight, food and water intake are recorded at two-day intervals.

Pathology:

Surviving animals are fasted overnight, weighed and humanely killed on the 15^{th} day using anesthetic ether. All test animals are subjected to gross necropsy.

Subchronic test for Vaeppam Pattai Kudineer :

This experiment evaluates the toxicity potential of Vaeppam Pattai Kudineer.

Method: Male and female Wistar rats weighing 180 ± 10 g are used for the present study. The animals are divided into five groups of six animals each. The dose of the preparation is calculated based on the body weight of the animal. The animals in Group I are administered with a single daily dose of 0.5 ml of Tween 80 orally for 20 days. The animals in Group II are administered with 50 $mg.kg^{-1}$b.w. of the Vaeppam Pattai Kudineer orally once daily for 20 days. The animals in Group III are administered with 100 $mg.kg^{-1}$b.w. of the Vaeppam pattai kudineer orally once daily for 20 days. The animals in Group IV and V are administered once daily with 200 and 400 $mg.kg^{-1}$b.w. of the Vaeppam pattai kudineer respectively for 20 days orally (Pieme,*et al* 2006, Joshi, *et al* 2007, Mythilypriya, *et al.,* 2007).(4,5,6)The animals are then weighed every five days, from the start of the treatment, to record the weight variation. At the end of the treatment, blood samples are collected by puncturing retro orbital plexus after mild anesthesia for biochemical analysis. The collected blood sample is centrifuged within 5 min of collection at 4000 g for 10 min to obtain plasma, which is analyzed for total cholesterol, total triglyceride, HDL-cholesterol levels,LDL-cholesterol,plasma glucose, alanine aminotransferase (ALT), aspartate aminotransferase (AST), creatinine and urea.

Results:

Acute toxicity study with Vaeppam pattai kudineer:

The acute toxicity of Vaeppam pattai kudineer was evaluated using OECD-423 guidelines. There was no mortality or morbidity observed in animals through the 15-days period following single oral administration at all selected dose levels of the Vaeppam pattai kudineer (Table-1). The animals did not show any changes in the general appearance during the observation period. Morphological characteristics such as fur, skin, eyes and nose appeared normal. No tremors, convulsion, salivation, diarrhea, lethargy or unusual behaviors such as self mutilation, walking backward and so forth were observed. Gait and posture, reactivity to handling or sensory stimuli, grip strength was also normal.

	Dose ($mg.kg^{-1}$)	**Sign of Toxicity ($ST.NB^{-1}$)**	**Mortality ($D.S^{-1}$)**
Group I	0	0/3	0/3
Group II	300	0/3	0/3
Group III	2000	0/3	3/3

Table.1. Acute toxicity study of Vaeppam pattai kudineer on experimental mice. The acute toxicityof Vaeppam pattai kudineer on experimental mice was tested using OECD-423 guidelines, where ST- sign of toxicity; NB- normal behaviour; D- died; S-survive. Values are expressed as number of animals (n=3).

Effect of Vaeppam pattai kudineer inSubchronic Toxicity :

Vaeppam pattai kudineer were evaluated for subchronic toxicity.

Effect of Vaeppam pattai kudineer on body weight changes in rats:

The effect of Vaeppam pattai kudineer was observed for their effect on the body weight changes from the study it was observed that, there was significant increase ($p<0.05$) in body weight in all the animals observed. The results are shown in Table.2.

Treatment	Day 1	Day 5	Day 10	Day 20
Control	184.19±5.43	185.40 ±6.12	194.10 ±6.30	194.6±6.28
Vaeppam pattai kudineer **50 mg.kg^{-1}**	191.34 ±6.23	194.30 ±6.44	195.48 ±6.75	195.30±6.82*
Vaeppam pattai kudineer **100 mg.kg^{-1}**	184.36 ±6.03	191.43 ±6.42	193.30 ±6.54	195.84±6.68*
Vaeppam pattai kudineer **200 mg.kg^{-1}**	193.25 ±7.03	195.20±6.34	195.48 ±6.58**	203.35±6.70**
Vaeppam pattai kudineer **400 mg.kg^{-1}**	184.54 ±6.37	191.35 ±6.65	193.15 ±6.65**	201.52±6.72**

Table.2. The effects of **Vaeppam pattai kudineer** on body weight changes in rats. A study on the effects of **Vaeppam pattai kudineer** on body weight changes in rats was carried out.. where, group I animals (GPI) were treated with normal saline (5 ml.kg^{-1}), group II animals (GPII) with 50 mg.kg^{-1} of **Vaeppam pattai kudineer**, group III animals (GPIII) with 100 mg.kg^{-1} of **Vaeppam pattai kudineer**, group IV animals (GPIV) with 200 mg.kg^{-1} of **Vaeppam pattai kudineer**, group V animals (GPV) with 400 mg.kg^{-1}**Vaeppam pattai kudineer**. The values are expressed as mean ± S.E.M. n=6. The results of group I were compared with other groups such as II, III, IV, and V. The statistical analysis was carried out using one way ANOVA method, where **P<0.01 *P<0.05.

Effect of Vaeppam pattai kudineer on kidney,heart, liver and brain in rats:

The effects of **Vaeppam pattai kudineer** on kidney, heart, liver and brain of the rats were observed. From the study it was clear that, significant (p<0.01) changes in the weights of various organs of the animals occurred with higher doses of the extract (400 mg.kg^{-1}bwt), but macroscopic examinations did not show any changes in colour of the organs of the treated animals compared with the control. The results are shown in Table.3.

Treatment	Heart (gms)	Kidney (gms)	Liver (gms)	Brain (gms)
Control	0.39 ± 0.04	0.79± 0.03	3.27± 0.14	0.69± 0.05
Vaeppam pattai kudineer@50 mg.kg^{-1}	0.41± 0.05	0.87± 0.05	3.37± 0.19	0.67± 0.03
Vaeppam pattai kudineer@100 mg.kg^{-1}	0.44± 0.06	0.87± 0.04	3.39±0.21	0.65± 0.08
Vaeppam pattai kudineer@ 200 mg.kg^{-1}	0.39± 0.03	0.80± 0.02	3.31± 0.22	0.73± 0.09
Vaeppam pattai kudineer@400 mg.kg^{-1}	0.42± 0.05	0.79± 0.02	3.33± 0.15	0.72± 0.12

Table.3. The effects of **Vaeppam pattai kudineer** on kidney, heart, liver and brain of the rats. A study on the effects of **Vaeppam pattai kudineer** on kidney, heart, liver and brain of the rats was tested. where, group I animals (GPI) treated with normal saline (5 ml.kg^{-1}), group II animals (GPII) with 50 mg.kg^{-1} of **Vaeppam pattai kudineer**, group III animals (GPIII) with 100 mg.kg^{-1} of **Vaeppam pattai kudineer**, group IV animals (GPIV) with 200 mg.kg^{-1} of **Vaeppam pattai kudineer**, group V animals (GPV) with 400 mg.kg^{-1}**Vaeppam pattai kudineer**. The values are expressed as mean ± S.E.M. n=6. The results of group I were compared with other groups such as II, III, IV, and V. The statistical analysis was carried out using one way ANOVA method, where **P<0.01.

Effect of Vaeppam pattai kudineer on biochemical profiles of rats:

The effect of **Vaeppam pattai kudineer** on various biochemical parameters of the experimental animal 'rats' were tested.From the study it was evident that, there was significant decrease ($p<0.05$) in the plasma glucose level in treated rats especially at higher dose (400 mg.kg^{-1}) compared with control rats. The control rats were administered only with 5 ml of normal saline. Significant decrease ($p<0.05$) in the plasma total cholesterol (TC), triglyceride (TG) and LDL-cholesterol levels were observed. But a significant increase ($p<0.05$) in HDL-cholesterol levels were observed in all the treated animals compared with the control animals. AST, ALT and ALP levels were also normal in the **Vaeppam pattai kudineer** treated animals.

From the results of biochemical study there was no evidence of severe toxicity associated with the administration of higher concentration of **Vaeppam pattai kudineer**. The results are shown in Table.4.

Treatment	**Glucose ($mg.dl^{-1}$)**	**Cholesterol ($mg.dl^{-1}$)**	**Triglyceride ($mg.dl^{-1}$)**	**HDL ($mg.dl^{-1}$)**	**LDL ($mg.dl^{-1}$)**
Control	94.42±1.74	29.05± 0.62	28.25±1.43	138.45±3.15	85.28±1.83
Vaeppam pattai kudineer@ 50 $mg.kg^{-1}$	93.50±1.62	25.30± 0.36*	11.36± 0.85*	176.40±3.65*	70.77±1.36
Vaeppam pattai kudineer@ 100 $mg.kg^{-1}$	91.44±1.52	23.65± 0.30*	13.32± 0.90*	165.30±3.40*	69.56±1.28
Vaeppam pattai kudineer@ 200 $mg.kg^{-1}$	89.30±1.35**	24.20± 0.38	15.40± 0.92*	184.34±3.70*	46.54±1.16
Vaeppam pattai kudineer@ 400 $mg.kg^{-1}$	92.28±1.43**	30.45± 0.48	18.30±1.15*	182.24±3.66*	45.32±1.03

Table.4. The effect of **Vaeppam pattai kudineer** on biochemical parameters such as glucose, cholesterol, triglyceride, HDL and LDL. A study on the effect of **Vaeppam pattai kudineer** on biochemical parameters such as glucose, cholesterol, triglyceride, HDL and LDL in rats was tested.where, group I animals (GPI) treated with normal saline (5 $ml.kg^{-1}$), group II animals (GPII) with 50 $mg.kg^{-1}$ of **Vaeppam pattai kudineer**, group III animals (GPIII) with 100 $mg.kg^{-1}$ of **Vaeppam pattai kudineer**, group IV animals (GPIV) with 200 $mg.kg^{-1}$ of, group V animals (GPV) with 400 $mg.kg^{-1}$**Vaeppam pattai kudineer**. The values are expressed as mean ± S.E.M. n=6. The results of group I were compared with other groups such as II, III, IV, and V. The statistical analysis was carried out using one way ANOVA method, where **P<0.01 *P<0.05

Treatment	AST ($IU.l^{-1}$)	ALT ($IU.l^{-1}$)	ALP ($IU.l^{-1}$)	TP ($g.l^{-1}$)	ALBUMIN ($g.l^{-1}$)
Control	335.3±11.60	80.4± 3.42	260.35± 8.57	78.36± 3.31	48.30±2.44
Vaeppam pattai kudineer@50 $mg.kg^{-1}$	325.4±10.52**	78.3± 2.90**	272.15±8.74**	78.30±3.20	45.24±2.29
Vaeppam pattai kudineer@ 100 $mg.kg^{-1}$	324.5±10.60**	75.3±2.92**	273.38±8.27**	88.12±3.80	46.30±2.44
Vaeppam pattai kudineer@ 200 $mg.kg^{-1}$	323.5±9.90	72.3± 2.38	273.20±8.33	79.35± 3.65	47.28±2.45
Vaeppam pattai kudineer@ 400 $mg.kg^{-1}$	325.4±9.94	72.6±2.45	273.42±8.41	79.30± 3.75	47.64±2.49

Table.5. The effects of **Vaeppam pattai kudineer** on biochemical parameters such as AST, ALT, ALP, TP and Albumin in rats. A study on the effects of **Vaeppam pattai kudineer** on biochemical parameters such as AST, ALT, ALP, TP and Albumin rats was tested. where, group I animals (GPI) were treated with normal saline ($5ml.kg^{-1}$), group II animals (GPII) with 50 $mg.kg^{-1}$ of HAEBD group III animals (GPIII) with 100 $mg.kg^{-1}$ of **Vaeppam pattai kudineer**, group IV animals (GPIV) with 200 $mg.kg^{-1}$ of **Vaeppam pattai kudineer**, and group V animals (GPV) with 400 $mg.kg^{-1}$**Vaeppam pattai kudineer** The values are expressed as mean ± S.E.M. n=6. The results of group I were compared with other groups such as II, III, IV, and V. The statistical analysis was carried out using one way ANOVA method, where **P<0.01 *P<0.05.

Effect of Vaeppam pattai kudineer on haematological parameters in rats :

The effects of **Vaeppam pattai kudineer** were observed for its effect on haematological parameters on the experimental rats. From the study it was evident that, a significant increase ($p<0.01$) were observed in the haemoglobin contents and RBC count in the group treated with 200 $mg.kg^{-1}$ body weight of **Vaeppam pattai kudineer** and a significant decrease of the parameters occurred in the group treated with 400 $mg.kg^{-1}$ b.w.t compared with the control. There was no significant change in the calcium level in all the treated animals compared to the control.

Treatment	Haemoglobin ($mg.dl^{-1}$)	RBC (10^6 /mm^3)	WBC (10^6 /mm^3)	Calcium ($mg.dl^{-1}$)
Control	18.53±1.28	9.32± 0.93	11.59± 0.90	9.48 ±0.60
Vaeppam pattai kudineer@ 50 $mg.kg^{-1}$	19.37±1.35*	9.40±1.05*	9.38± 0.82*	9.30 ±0.38
Vaeppam pattai kudineer@ 100 $mg.kg^{-1}$	19.22±1.84*	9.53±1.20*	8.37± 0.28*	9.32 ±0.45
Vaeppam pattai kudineer@ 200 $mg.kg^{-1}$	18.25±1.25*	8.42± 0.85*	11.61± 0.83*	9.60 ±0.56
Vaeppam pattai kudineer@ 400 $mg.kg^{-1}$	18.21±1.23*	8.51± 0.92*	10.88±0.75*	9.69 ±0.64

Table.6. The effect of **Vaeppam pattai kudineer** on haematological parameters such as HB, Calcium, RBC and WBC in rats. A study on the effect of **Vaeppam pattai kudineer** on haematological parameters such as Hb, RBC, WBC, Calcium in rats was tested. where, group I animals (GPI) treated with normal saline (5 $ml.kg^{1}$), group II animals (GPII) with 50 $mg.kg^{-1}$ of **Vaeppam pattai kudineer**, group III animals (GPIII) with 100 $mg.kg^{-1}$ of **Vaeppam pattai kudineer**, group IV animals (GPIV) with 200 $mg.kg^{-1}$ of **Vaeppam pattai kudineer**, and group V animals (GPV) with 400 $mg.kg^{-1}$**Vaeppam pattai kudineer**.

The values are expressed as mean ± S.E.M. n=6. The results of group I were compared with other groups such as II, III, IV and V. The statistical analysis was carried out using one way ANOVA method, where *P<0.05.

Discussion:

The evaluation of sub-chronic and chronic dosing in experimental animals may be more relevant in determining the overall toxicity of the plant preparation. The highest overall concordance of toxicity in animals in comparison with humans is with hematological, gastrointestinal, and cardiovascular adverse effects whiles certain adverse effects in humans, especially hypersensitivity and idiosyncratic reactions, are poorly correlated with toxicity observed in animals (Olson, *et al*., 2000).(7)

In the present study, where the acute toxicity study of **Vaeppam pattai kudineer** was carried out as per OECD-423 guidelines, no mortality was observed in both the animals of control group as well as animals treated with a maximum dose of 2000 $mg.kg^{-1}$. Hence, $1/10^{th}$ of 2000 $mg.kg^{-1}$ i.e. 200 $mg.kg^{-1}$ of dose was selected as a minimum dose for sub-acutetoxicity study (Abu TahaNael, *et al.,* 2008).(8)

The results of sub-acute toxicity study shows that there was no significant change in animal behaviour due to the absence of toxicity. The animals treated with **Vaeppam pattai kudineer** showed normal growth pattern and body weight compared with control rats treated with normal saline. So the changes in body weight can be used as an indicator of adverse effects of drugs and chemicals (Tofovic and Jackson, 1999; Raza, *et al.*, 2002; Teo, 2002).(9,10,11)

The changes in enzymes like ALP, AST and ALT levels show liver impairment, due to toxicity (Hayes, 1989).(12) Serum cholesterol and proteins mainly regulated via synthesis in the liver and increase or decrease in serum concentrations of constituents suggest liver toxicity. The results of the present study were assessed after 28 days of administration of **Vaeppam pattai kudineer**, and it was found that **Vaeppam pattai kudineer** at all concentrations do not produce liver damage.

There was a slight decrease in plasma glucose level, when higher doses of **Vaeppam pattai kudineer** (400 $mg.kg^{-1}$) were administered in the treated rats.

Analysis of blood parameters is likely to risk evaluation as the change in hematological system has a higher predictive value for human toxicity, when data are translated from animal studies (Olson, *et al*., 2000).(7) After 28 days of treatment, there were no significant changes in the haematological parameters between control and treated groups. No significant changes in the levels of WBC, RBC were observed between control and test groups following repeated administration of **Vaeppam pattai kudineer**. Interestingly, significant increase in the levels of hemoglobin was found in treatment with **Vaeppam pattai kudineer** with a higher dose of 400 $mg.kg^{-1}$. The possible reason could be that one of the constituents **Vaeppam pattai kudineer** may increase absorption of iron.

The overall results suggest that **Vaeppam pattai kudineer** are non toxic to the haaematopoietic and leucopoietic system. The haematopoietic and leucopoietic systems are the most sensitive targets for toxic compounds and an important index of physiological and pathological status in man and animal (Adeneye, *et al*., 2006).(13) Therefore, it is possible to assume that the **Vaeppam pattai kudineer** is non haematotoxic.

ANNEXURE – V

PROFORMA OF CASE SHEET
GOVERNMENT SIDDHA MEDICAL COLLEGE & HOSPITAL,
PALAYAMKOTTAI, TIRUNELVELI DISTRICT
DEPARTMENT OF POTHU MARUTHUVAM

PRE CLINICAL AND PHASE II RANDOMIZED CLINICAL TRIAL ON THANDAGA VATHAM (LUMBAR SPONDYLOSIS) WITH VAEPPAM PATTAI KUDINEER

FORM-I
(SCREENING AND SELECTION PROFORMA)

1. Name_____ 2. Age_____ 3.Gender_____ 4.Phone no _____

5. OP No/IP No _____ 6. S No._____ 7. Occupation _____

8. Income _____

INCLUSION CRITERIA:

- Age : 30 - 60Yrs
- Sex : Both Male and Female
- Patients having symptoms of pain in the low back area, radiating pain to buttocks and lower limbs
- Stiffness present in the low back area
- Exacerbation of pain on movements
- Pain increased on forward bending ,tingling sensation
- Patients who are willing for admission and stay in IP for minimum 20-30 days or willing to attend OPD
- Patients who are willing to undergo radiological investigation and give blood and urine samples for laboratory investigation.
- Patient willing to sign the informed consent stating that he/she will consciously stick to the treatment during 30 days but can opt out of the trial of his/her own conscious discretion.
- Patients complaining of Back pain functional scale score ranging below 30.

EXCLUSION CRITERIA:

- Age below 30 years and above 60 years
- Diabetes mellitus
- Auto immune disease like SLE, RA
- Chronic kidney disease
- Fracture of spine
- Tuberculosis of spine
- Congential spino vertebral deformities
- Cardiac disease
- Endocrine disorders
- Malignancy
- Systemic hypertension
- Pregnancy and lactation
- Osteomyelitis
- Liver disorder
- Chronic alcoholic and smokers

Date:

Station:

Signature of the Investigator:

Signature of the Guide : Signature of the HOD:

GOVERNMENT SIDDHA MEDICAL COLLEGE & HOSPITAL

PALAYAMKOTTAI, TIRUNELVELI DISTRICT

DEPARTMENT OF POTHU MARUTHUVAM

PRE CLINICAL AND PHASE-II RANDOMIZED CLINICAL TRIAL ON

THANDAGA VATHAM (LUMBAR SPONDYLOSIS)

VAEPPAM PATTAI KUDINEER

FORM-l A

HISTORY PROFORMA ON ENROLLMENT

1. Serial No of the case: _____ 2. OP/IP No:_____

3. Name: _____ 4. Gender: Male ☐ Female ☐

5. Age (years): _____

6. Address:

7. a). Occupation: ---------- b). Nature of work----------

8. Educational Status: a). Illiterate b). Literate

9. Height: ---------- cms 10. Weight: ----------kg

11. Complaints and Duration:

_____

_____

_____

12. Past History:

Systemic Hypertension :

Diabetes mellitus :

Bronchial Asthma :

PT :

MCTD :

13. Habits**:**

a). Smoking : 1. Yes duration _____ years Number: _____ 2. No

b). Alcoholism: 1. Yes duration _____ years Quantity: ____ ml 2. No

c). Tobacco chewing: 1. Yes duration _____ years 2.No

d). Betel chewing: 1. Yes duration _____ years 2.No

14. Dietary style: a). Pure vegetarian b.) Non-vegetarian

15. Drug history: Had the patient been treated before with allopathy drug?

1). Yes 2). No

16. Marital status: 1. Married 2. Unmarried

17. Family history:

Whether this problem runs in family? 1. Yes 2.No

If yes, mention the relationship of affected person(s) - _____

18. Bowel habits & micturition: Normal

History of habitual constipation 1. Yes 2. No

History of chronic diarrhoea 1. Yes 2. No

History of recurrent UTI 1. Yes 2. No

19. Psychological state: Normal Anxiety Depression

Date :

Station :

Signature of the Investigator:

Signature of the Guide: **Signature of the HOD**

GOVERNMENT SIDDHA MEDICAL COLLEGE & HOSPITAL,
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PRECLINICAL AND PHASE-II RANDOMIZED CLINICAL TRIAL ON
THANDAGA VATHAM (LUMBAR SPONDYLOSIS) WITH
VAEPPAM PATTAI KUDINEER

FORM-II & II-A

CLINICAL ASSESSMENT ON ENROLLMENT AND ON VISITS

1.S.No.: _____ 2. OP/IP No.: _____ 3.Age: _____

4. Name: _____ 5. Gender: _____

6. Occupation: _____ 7. Date of assessment: _____

SIDDHA SYSTEM OF EXAMINATION

1. ENVAGAI THERVUGAL (EIGHT-FOLD EXAMINATION):

I. NAADI (PULSE PERCEPTION):

	0st Day	**07th Day**	**15th Day**	**21st Day**	**28th Day**	**30th Day**
Vali						
Azhal						
Iyyam						
ValiAzhal						
Azhalvali						
Iyyavali						
ValiIyyam						
AzhalIyyam						
IyyaAzhal						

II. NAA (TONGUE):

	0th Day	07th Day	14th Day	21st Day	28th Day	30th Day
Colour	Dark/ Yellow/ Red/ Pale	Dark/ Yellow/ Red/ Pale	Dark/ Yellow/ Red/ Pale	Dark/ Yellow/ Red/ Pale	Dark/ Yellow/ Red/ Pale	Dark/ Yellow/ Red/ Pale
Taste	Sweet/ Bitter/ Sour/ Pungent/ None	Sweet/ Bitter/ Sour/ Pungent/ None	Sweet/ Bitter/ Sour/ Pungent/ None	Sweet/ Bitter/ Sour/ Pungent/ None	Sweet/ Bitter/ Sour/ Pungent/ None	Sweet/ Bitter/ Sour/ Pungent/ None
Coating	Present/ Absent	Present/ Absent	Present/ Absent	Present/ Absent	Present/ Absent	Present/ Absent
Fissure	Present/ Absent	Present/ Absent	Present/ Absent	Present/ Absent	Present/ Absent	Present/ Absent
Saliva	Normal/ Increased/ Decreased	Normal/ Increased/ Decreased	Normal/ Increased/ Decreased	Normal/ Increased/ Decreased	Normal/ Increased/ Decreased	Normal/ Increased/ Decreased
Dryness	Present/ Absent	Present/ Absent	Present/ Absent	Present/ Absent	Present/ Absent	Present/ Absent
Glossitis	Present/ Absent	Present/ Absent	Present/ Absent	Present/ Absent	Present/ Absent	Present/ Absent

III. NIRAM (COLOUR COMPLEXION):

0th Day	07th day	14th Day	21stDay	28th Day	30th day
Dark/ Yellow/ tinted/Pale	Dark/ Yellow/ tinted/Pale	Dark/ Yellow/ tinted/Pale	Dark/ Yellow/ tinted /Pale	Dark/ Yellow/ tinted/Pale	Dark/ Yellow/ tinted/Pale

IV. MOZHI (VOICE):

0th Day	07th day	14th Day	21stDay	28th Day	30th day
Medium/ High/ Low / Pitched	Medium/ High/ Low/ Pitched	Medium/ High/ Low/ pitched	Medium/ High/ Low/ pitched	Medium/ High/ Low/ pitched	Medium/ High/ Low/ pitched

V. VIZHI (EYE) (PALPEBRAL CONJUNCTIVA):

0th Day	07th day	14th Day	21stDay	28th Day	30th day
Dark/ Yellow / Red/ Pale	Dark/ Yellow/ Red/ Pale	Dark/ Yellow/ Red/ Pale	Dark/ Yellow/ Red/ Pale	Dark/ Yellow/ Red/ Pale	Dark/ Yellow/ Red/ Pale

VI. MALAM (BOWEL HABITS / STOOLS):

	0th Day	07th Day	14th Day	21stDay	28th Day	30th day
Colour	Dark/ Yellow/ Red/ Pale	Dark/ Yellow/ Red/ Pale	Dark/ Yellow/ Red/ Pale	Dark/ Yellow/ Red/ Pale	Dark/ Yellow/ Red/ Pale	Dark/ Yellow/ Red/ Pale
Consistency	Solid/ Semisolid/ Watery	Solid/ Semisolid/ Watery	Solid/ Semisolid/ Watery	Solid/ Semisolid/ Watery	Solid/ Semisolid/ Watery	Solid/ Semisolid/ Watery
Constipation	Present/ Absent	Present/ Absent	Present/ Absent	Present/ Absent	Present/ Absent	Present/ Absent
Diarrhoea	Present/ Absent	Present/ Absent	Present/ Absent	Present/ Absent	Present/ Absent	Present/ Absent

VII. URINE EXAMINATION:

NEER KURI	0th Day	07th day	14th Day	21stDay	28th Day	30th Day
Niram (Colour)	White/ Yellowish/ Straw coloured/ Crystal clear	White/ Yellowish/ Straw Coloured/ Crystal clear	White/ Yellowish/ Straw coloured/ Crystal clear	White/ Yellowish/ Straw coloured/ Crystal clear	White/ Yellowish/ Straw coloured/ Crystal clear	White/ Yellowish/ Straw coloured/ Crystal clear
Manam (Odour)	Present/ Absent	Present/ Absent	Present/ Absent	Present/ Absent	Present/ Absent	Present/ Absent
Nurai (Froth)	Nil/ Reduced/ Increased	Nil/ Reduced/ Increased	Nil/ Reduced/ Increased	Nil/ Reduced/ Increased	Nil/ Reduced/ Increased	Nil/ Reduced/ Increased
Edai (Sp. gravity)	Normal/ Increased/ Reduced	Normal/ Increased/ Reduced	Normal/ Increased/ Reduced	Normal/ Increased/ Reduced	Normal/ Increased/ Reduced	Normal/ Increased/ Reduced

Enjal (Deposits)	Present/ Absent	Present/ Absent	Present/ Absent	Present/ Absent	Present/ Absent	Present/ Absent
Volume	Normal/ Increased/ Reduced	Normal/ Increased/ Reduced	Normal/ Increased / Reduced	Normal/ Increased/ Reduced	Normal/ Increased/ Reduced	Normal/ Increased/ Reduced

NEI KURI	**0^{th} Day**	**7th Day**	**14th Day**	**21stDay**	**28th Day**	**30th Day**
Serpentine fashion						
Annular/Ringed fashion						
Pearlbeaded fashion						
Mixed fashion						
Other fashion						

VIII. SPARISAM (PERCEPTION):

0^{th} Day	**7th day**	**14th Day**	**21stDay**	**28thDay**	**30th day**
Warmth/ Cold/ Sweat	Warmth/ Cold/ Sweat	Warmth/ Cold/ Sweat	Warmth/ Cold/ Sweat	Warmth/ Cold/ Sweat	Warmth/ Cold/ Sweat

2. THEGI (BODY CONSTITUTION):

Vatham Thegi		Kapham Thegi	
Pitham Thegi		Kalappu Thegi	

3. NILAM (LAND WHERE PATIENT LIVED MOST):

Kurinji ☐ Mullai ☐ Marutham ☐ Neithal ☐ Palai ☐

(Hilly terrain) (Forest range) (Plains) (Coastal) (Arid regions)

4. KAALAM:

Kaarkalam ☐ Pinpanikalam ☐

Koothirkalam ☐ Ilavenil ☐

Munpanikalam ☐ Muthuvenil ☐

5. GUNAM:

Sathuva Gunamm ☐ Raso Gunam ☐ Thamo Gunam ☐

6. IMPORIGAL (SENSORY ORGANS):

	0th Day	**7th Day**	**14th Day**	**21stDay**	**28th Day**	**30th Day**
Mei (Skin)						
Vai (Buccal Cavity)						
Kann (Eye)						
Sevi (Ear)						
Mooku (Nose)						

7. KANMENDRIYAM (MOTOR ORGANS):

	0th Day	**7th Day**	**14th Day**	**21stDay**	**28th Day**	**30th Day**
Kai (Upper Limb)						
Kaal (Lower Limbs)						
Vai (Buccal Cavity)						
Eruvaai (Excretory Organs)						
Karuvaai (Reproductive Organs)						

8. KOSANGAL (SHEATH):

	0th Day	**7th Day**	**14th Day**	**21stDay**	**28th Day**	**30th Day**
AnnamayaKosam						
Pranamayakosam						
Manomayakosam						
Vignanamayakosam						
Ananthamayakosam						

9. MUKKUTRAM (CONDITION OF THREE HUMORS):

a). VATHAM:

	0th Day	**7th Day**	**14th Day**	**21stDay**	**28th Day**	**30th Day**
Praanan						
Abaanan						
Viyaanan						
Udhaanan						
Samanan						
Naagan						
Koorman						
Kirukaran						
Devathathan						
Dhananjeyan						

b). PITHAM:

	0th Day	**7th day**	**14th Day**	**21stDay**	**28th Day**	**30th Day**
Anala Pitham						
Ranjagam						
Saathagam						
Praasagam						
Aalosagam						

c) KAPHAM:

	0th Day	**7th Day**	**14th Day**	**21stDay**	**28th Day**	**30th Day**
Avalambagam						
Kilaethagam						
Pothagam						
Tharpagam						
Santhigam						

10. SEVEN THATHUS (7 SOMATIC COMPONENTS):

	0th Day	**7th Day**	**14th Day**	**21st Day**	**28th Day**	**30th Day**
Saaram (Chyme)						
Senneer (Blood)						
Oon (Muscle)						
Kozhuppu (Fat)						
Enbu (Bones)						
Moolai (Bone marrow)						
Sukkilam (Spermatoza) / Suronitham (Ovum)						

11. SYSTEMIC EXAMINATION:

	0th Day	**7th Day**	**14th Day**	**21st Day**	**28th Day**	**30th Day**
Locomotor system						
Cardiovascular system						
Respiratory system						
Gastro intestinal system						
Central nervous system						
Urogenital system						
Endocrine system						

12. GENERAL EXAMINATION:

	0th Day	**7th Day**	**14th Day**	**21st Day**	**28th Day**	**30th Day**
Height (cm)						
Weight (kg)						
Temperature (F^0)						
Pulse rate (per min)						
Heart rate (per min)						
Respiratory rate (per min)						
Blood pressure (mm/Hg)						
Pallor						
Clubbing						
Jaundice						
Cyanosis						
Lymphadenopathy						
Jugular vein pulsation						
Pedal oedema						

13. CLINICAL SYMPTOMS:

COMPLAINTS	0th Day	7th Day	15th Day	30th Day
Pain in low back area				
Nature of pain				
Onset of pain				
Radiating pain to buttocks				
Radiating pain in right lower limb				
Radiating pain in left lower limb				
Pain increased on forward bending				
Sensory loss on affected area				
Numbness				
Tenderness				
Restriction of movements				
Burning sensation in lower extremities				

The Back pain function scale (BPFS) of Stratford et al over view

Stratford et al developed the Back Pain Function Scale (BPFS) to evaluate functional ability in patients with back pain. The authors are from McMaster University Appalachian Physical Therapy (Georgia) and Virginia Commonwealth University.

Measures:

(1) Any of your usual work housework or school activities

(2) Your usual hobbies recreational or sporting activities

(3) Performing heavy activities around your home

(4) Bending or stooping

(5) Putting your shoes or socks (or stockings or pantyhose)

(6) Lifting a box of groceries from the floor

(7) Sleeping

(8) Standing for 1 hour

(9) Walking 1 mile

(10)Going up or down 2 flights of stairs (about 20 steps)

(11)Sitting for 1 hour

(12)Driving for 1 hour

Responses Points:

unable to perform activity 0

extreme difficulty1

quite a bit of difficulty 2

moderate difficulty 3

a little bit of difficulty 4

no difficulty 5

Total score = SUM (points for 12 measures)

Adjusted total score = (total score) / 60 Interpretation:

•Minimum score: 0

• Maximum score: 60

• Maximum adjusted score: 1 (100%)
• The higher the score the greater the patient's functional ability.

Total Score (Adjusted) Interpretation

0 (0%)	unable to perform any activity
60 (100%)	no difficulty in any activity

References:

Stratford PW Binkley JM et al. Development and initial validation of the Back Pain

Functional Scale.Spine.2000; 25: 2095-2102 (Appendix A page 2101).

14. BACK PAIN FUNCTIONAL SCALE SCORE:

SL.NO	PATIENT'SACTIVITIES	NORMAL SCORE	PATIENT'S SCORE
1	Any of your usual work house work or school activities	5	
2	Your usual hobbies recreational or sporting activities	5	
3	Performing heavy activities around your house	5	
4	Bending or stooping	5	
5	Putting your shoes or socks	5	
6	Lifting a box of groceries from the floor	5	
7	Sleeping	5	
8	Standing for 1 hour	5	
9	Walking 1 mile	5	
10	Going up or down2 flights of stairs (20 steps)	5	
11	Sitting for 1 hour	5	
12	Driving for 1 hour	5	

(Minimum Score- 0, Maximum Score-60)

PAIN SCORE

BEFORE TREATMENT	AFTER TREATMENT

15. CLINICAL EXAMINATION:

A. INSPECTION:

	0th Day	7th Day	14th Day	21st Day	28th Day	30th Day
Attitude						
Muscle						
Wasting						
Swelling						

B.PALPATION:

	0th Day	**7th Day**	**14th Day**	**21st Day**	**28th Day**	**30th Day**
Tenderness						
Muscle spasm						
Local heat						
Local lymphadenopathy						
Pitting oedema						
Joint stiffness						

C.MOVEMENTS:

	0th Day	**7th Day**	**14th Day**	**21st Day**	**28th Day**	**30th Day**
Stiffness						
Restriction of movements						
Rotation						
Flexion						
Extension						
Lateral bending						

Date:

Station:

Signature of the Investigator:

Signature of the Guide : Signature of the HOD

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PRE CLINICAL AND PHASE-II RANDOMIZED CLINICAL TRIAL ON

THANDAGA VATHAM (LUMBAR SPONDYLOSIS) WITH

VAEPPAM PATTAI KUDINEER

FORM-III

LABORATORY INVESTIGATIONS

1	Sl. No.		2	OP/IP No	
3	Bed No		4	Name	
5	Age		6	Gender	

I. BLOOD:

Sl. No.	Details	Before Treatment	After Treatment
1	TC (cells/mm)		
2	DC (%)		
	a) Neutrophils		
	b) Lymphocytes		
	c) Monocytes		
	d) Eosinophils		
3	ESR(mm)		
	a) 1/2 hour		
	b) 1 hour		
4	Haemoglobin		
5	Blood sugar		
6	Blood urea		
7	Serum creatinine		
8	Serum cholesterol		
9	Serum Uric acid		
10	RA Factor		

II. URINE:

Sl. No.	Details	Before Treatment	After Treatment
1.	Albumin		
2.	Sugar		
3.	Deposit		
	a). Epithelial cells		
	b). Pus cells		
	c). Red blood cells		
	d). Casts/Crystals		

III. X-RAY OF THE AFFECTED JOINTS:

Region affected	Impression: Before Treatment	Impression: After Treatment

Date :

Station :

Signature of the Investigator:

Signature of the Guide : Signature of the HOD

GOVERNMENT SIDDHA MEDICAL COLLEGE & HOSPITAL,
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DEPARTMENT OF POTHU MARUTHUVAM
PRECLINICAL AND PHASE-II RANDOMIZED CLINICAL TRIAL ON
THANDAGA VATHAM (LUMBAR SPONDYLOSIS) WITH
VAEPPAM PATTAI KUDINEER

FORM-IV

CERTIFICATE BY INVESTIGATOR

I certify that I have disclosed all details about the study in the terms readily understood by the patient.

Date: …….. Signature: …….

Name: ……..

CONSENT BY PATIENT

I have been informed to my satisfaction, by the attending physician, the purpose of the clinical trial, and the nature of drug treatment and follow-up including the laboratory investigations to be performed to monitor and safeguard my body functions.

I am aware of my right to opt out of the trial at any time during the course of the trial without having to give the reasons for doing so.

I, exercising my free power of choice, hereby give my consent to be included As a subject in the clinical trial of **VAEPPAM PATTAI KUDINEER for the management of THANDAGA VATHAM (LUMBAR SPONDYLOSIS).**

Date: Signature: ……

Name: …….

Signature of Witness: …….

Name…….. ……

Relationship: …….

அரசுசித்தமருத்துவக் கல்லூரி மற்றும் மருத்துவமனை

பாளையங்கோட்டை, திருநெல்வேலிமாவட்டம்.

பட்டமேற்படிப்பு பொது மருத்துவத்துறை

தண்டகவாதம் நோய்க்கு மருந்தாக

வேப்பம்பட்டை குடிநீர்

பரிகரிப்புத் திறனைக் கண்டறியும் மருத்துவ ஆய்வு ஒப்புதல் படிவம்

ஆய்வாளரின் சான்றிதழ்

நான் இந்த ஆய்வு குறித்து விபரங்களையும் நோயாளிக்குப் புரியும் வகையில் எடுத்துரைத்தேன் எனஉறுதியளிக்கிறேன்.

கையொப்பம்

பெயர்:

தேதி :

இடம் :

நோயாளியின் ஒப்புதல்

என்னிடம் இந்த மருத்துவ ஆய்வின் காரணத்தையும், மருந்தின் தன்மைமற்றும் மருத்துவ வழிமுறையைப் பற்றியும் தொடர்ந்து எனது உடல் இயக்கத்தை கண்காணிக்கவும், அதனைப் பாதுகாக்கவும் பயன்படும் மருத்துவ ஆய்வுக்கூட பரிசோதனைகள் பற்றி திருப்தி அளிக்கும் வகையில் ஆய்வுமருத்துவரால் விளக்கிக் கூறப்பட்டது.

நான் இந்த மருத்துவ ஆய்வின் போது காரணம் எதுவும் கூறாமல் எப்பொழுது வேண்டுமானாலும் இந்த ஆய்விலிருந்து என்னை விடுவித்துக் கொள்ளும் உரிமையை தெரிந்திருக்கிறேன்.

நான் என்னுடைய சுதந்திரமாக தேர்வு செய்யும் உரிமையைக் கொண்டு **தண்டகவாதம்** நோய்க்கு மருந்தாக **வேப்பம்பட்டை குடிநீர்** பரிகரிப்புத் திறனைக் கண்டறியும் மருத்துவ ஆய்விற்கு என்னை உட்படுத்த ஒப்புதல் அளிக்கிறேன்.

தேதி :

இடம் :

கையொப்பம்

பெயர்:

சாட்சியின் கையொப்பம்

பெயர்:

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THANDAGA VATHAM (LUMBAR SPONDYLOSIS) WITH
VAEPPAM PATTAI KUDINEER

FORM- IV A

WITHDRAWAL FORM

Name: _____ OPD/ IPD number: _____

Age : _____ Gender: _____ Occupation: _____

Date of trial commencement: _____

Date of withdrawal from trial: _____

Reasons for withdrawal:

- Long absence at reporting : Yes ☐ No ☐
- Irregular treatment : Yes ☐ No ☐
- Shift of locality : Yes ☐ No ☐
- Increase in severity of symptoms : Yes ☐ No ☐
- Development of severe adverse drug reactions: Yes ☐ No ☐

Date :

Station :

Signature of Investigator **Signature of HOD**

Signature of Guide

GOVERNMENT SIDDHA MEDICAL COLLEGE & HOSPITAL,
PALAYAMKOTTAI, TIRUNELVELI DISTRICT
DEPARTMENT OF POTHU MARUTHUVAM
PRECLINICAL AND PHASE-II RANDOMIZED OPEN LABELLED CLINICAL STUDY ON THANDAGA VATHAM (LUMBAR SPONDYLOSIS) WITH VAEPPAM PATTAI KUDINEER

FORM-IV B

PATIENT INFORMATION SHEET

- It is a degenerative disc disease.
- This disease is not contagious.
- It primarily affects jointsand typically results in low back pain, radiating pain to lower limbs andstiffness.
- Many herbal and mineral siddha medicines are currently practiced by the siddha practitioners for this disease.
- The trial drug is prescribed only with the evidence of Siddha literature.
- The trial drug is prepared at the Gunapadam Lab of Government Siddha Medical College & Hospital, Palayamkottai under the direct supervision of teaching faculties of PothuMaruthuvam and Gunapadam Department.

Details of the trial drug:

Drug	:	**VAEPPAM PATTAI KUDINEER**
Dose	:	50 ml twice a day.
Duration	:	30 days.

அரசினர் சித்தமருத்துவக் கல்லூரி மற்றும் மருத்துவமனை

பாளையங்கோட்டை,திருநெல்வேலிமாவட்டம்.

பட்டமேற்படிப்பு பொது மருத்துவத்துறை

வேப்பம்பட்டை குடிநீரின் பரிகரிப்புத் திறனைக்

கண்டறியும் மருத்துவஆய்வுதகவல் படிவம்

- தண்டகவாத நோயானது முதுகு என்பு தேய்மானத்தால் ஏற்படக்கூடிய நோயாகும்.
- இந்நோயில் முதுகுஎன்பில் வலி, வலியானது இரு கால்களுக்கு பரவல், விறைப்பு தன்மை ஆகியன காணப்படும்.
- சித்தமருத்துவத்தில் அதிகஅளவு மூலிகைகள் மற்றும் தாதுப் பொருட்கள் இந்நோய்க்கு மருந்தாகப் பயன்படுகிறது.
- ஏற்கனவே உபயோகத்தில் உள்ள இது போன்ற மருந்துகள் இதுவரை நோயாளிகளிடம் எந்தவித பக்கவிளைவுகளை ஏற்படுத்தவில்லை.
- இந்த மருந்து சிறப்பாக தண்டகவாதம் நோய்க்காகஅங்கீகரிக்கப்பட்ட சித்தமருத்துவ நூலில் பெறப்பட்டுள்ளது.
- மேற்கண்ட மருந்தானது அரசினர் சித்தமருத்துவக் கல்லூரி மற்றும் மருத்துவமனை, பாளையங்கோட்டையில் உள்ள பட்ட மேற்படிப்பு குணப்பாடம் மருந்து செய் ஆய்வகத்தில் செய்து முடிக்கப்பட்டது.
- இந்த ஆராய்ச்சி சம்பந்தமாக சில கேள்விகளைக் கேட்கவும், தேவையான ஆய்வக பரிசோதனைக்குத் தங்களை உட்படுத்தவும் உள்ளேன்.
- இது சம்பந்தமாக தங்களது அனைத்து விபரங்களும் ரகசியமாக வைக்கப்படும் என்று உறுதியளிக்கிறேன்.
- இந்த ஆராய்ச்சியின் போது உடலுக்கு வேறு பாதிப்பு ஏற்படும் பட்சத்தில் அரசினர் சித்தமருத்துவக் கல்லூரி மற்றும் மருத்துவமனை, பாளையங்கோட்டையில் தக்க சிகிச்சை அளிக்கப்படும்.
- இந்த ஆராய்ச்சியில் சேர்ந்த பிறகு உங்களுக்கு விருப்பம் இல்லையெனில் எப்பொழுது வேண்டுமானாலும் விலகிகொள்ளலாம்.

மேலும் இந்த ஆராய்ச்சிக்கு IEC அனுமதிச் சான்று பெறப்பட்டுள்ளது.

GOVERNMENT SIDDHA MEDICAL COLLEGE & HOSPITAL
PALAYAMKOTTAI, TIRUNELVELI DISTRICT
DEPARTMENT OF POTHU MARUTHUVAM
PRE CLINICAL AND PHASE-II RANDOMIZED CLINICAL TRIAL ON THANDAGA VATHAM (LUMBAR SPONDYLOSIS) WITH VAEPPAM PATTAI KUDINEER

FORM–IV C

ADVERSE DRUG REACTION FORM

Name: _____ OPD/ IPD No: _____

Age: _____ Gender: ____ Occupation: _____

Date of trial commencement: _____

Date of withdrawal from trial: _____

Description of adverse reaction:
_____

_____

Date :
Station :

Signature of Investigator **Signature of HOD**

Signature of Guide

GOVERNMENT SIDDHA MEDICAL COLLEGE & HOSPITAL,

PALAYAMKOTTAI, TIRUNELVELI DISTRICT

DEPARTMENT OF POTHU MARUTHUVAM

DISCHARGE CASE SHEET PROFORMA FOR

"THANDAGA VATHAM (LUMBAR SPONDYLOSIS)"

FORM-IV D

I.P. No.	:	Occupation	:
Bed No.	:	Income	:
Ward No.	:	Nationality	:
Name	:	Religion	:
Age / Sex	:	Date of Admission	:
Address	:	Date of Discharge	:
Diagnosis	:		
No. of Days treated	:		

CLINICAL PROGNOSIS:

AT THE TIME OF ADMISSION	AT THE TIME OF DISCHARGE

Medical Officer Signature:
PROF / H.O.D

GOVERNMENT SIDDHA MEDICAL COLLEGE & HOSPITAL,
PALAYAMKOTTAI, TIRUNELVELI DISTRICT
DEPARTMENT OF POTHU MARUTHUVAM
PRE CLINICAL AND PHASE-II RANDOMIZED CLINICAL TRIAL ON
THANDAGA VATHAM (LUMBAR SPONDYLOSIS) WITH
VAEPPAM PATTAI KUDINEER

FORM-IV E

(DRUG COMPLIANCE FORM)

Name : _____ Age/ Sex : _____ S. No : _____

OPD/ IPD No : _____ Date : _____ Bed No : _____

Name of The Drug : **VAEPPAM PATTAI KUDINEER**

Drugs issued date :

Drugs returned date :

Days	DATE	DRUG TAKEN TIME	
		MORNING TIME	EVENING TIME
Day 1			
Day 2			
Day 3			
Day 4			
Day 5			
Day 6			
Day 7			
Day 8			
Day 9			
Day 10			
Day 11			
Day 12			
Day 13			

Day 14			
Day 15			
Day 16			
Day 17			
Day 18			
Day 19			
Day 20			
Day 21			
Day 22			
Day 23			
Day 24			
Day 25			
Day 26			
Day 27			
Day 28			
Day 29			
Day 30			

Date :

Station :

Signature of Investigator **Signature of HOD**

Signature of Guide

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(For IAE / CPCSEA usage)

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Date received after modification (if any)	:	NA
Date received after second modification (if any)	:	NA
Approval date	:	15.02.2017
Expiry date	:	31.07.2017
Name of IAEC / CPCSEA chairperson	:	Dr. N. CHIDAMBARANATHAN

Date: 15.02.2017

15/2/17

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CONTINUING MEDICAL EDUCATION PROGRAMME

Conducted by

Post Graduate Department of Pothu Maruthuvam

This Certificate is awarded to Dr / ~~Mr~~ / ~~Mrs~~ L. JENSIN BRINTHA .....

has participated in the CME Programme held on 13.06.2018 at Conference Hall Special Therapy Wing, Government Siddha Medical College, Palayamkottai, Tirunelveli. This Programme is focussed on

"NON COMMUNICABLE DISEASES"

Prof. Dr. A. MANOHARAN, M.D.(s) Ph.D.,
Head, Department of Pothu Maruthuvam (PG)
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PRINCIPAL
Government Siddha Medical College, Palayamkottai.

GOVERNMENT SIDDHA MEDICAL COLLEGE

PALAYAMKOTTAI

Certificate of Botanical Authenticity

Certified the following plant drugs used in Siddha formulation Veppampattai kudineer (Internal) for the management ofThandaga vatham (Lumbar spondylosis) taken up for Post Graduation Dissertation Studies by Dr.L.Jensin Brintha (Reg No.321511003) PG Dept. of Pothu Maruthuvam are correctly identified and authenticated through Visual Inspection / Organoleptic Characters / Experience, Education and Training Morphology and Taxonomical methods.

Ingrediant of Veppam pattai kudineer

S.N	Name	Botanical Name	Family	Part used
1.	Veppam pattai	*Azadiracta indica*	Meliaceae	Bark
2.	Thippili	*Piper longum*	Piperaceae	Flower Bud

Station: Palayamkottai,

Date: 8.2.17

Authorized Signature 8/2/17

Dr. S. SUTHA, M.Sc.,M.Ed.,Ph.D.,
Associate Professor
Dept. of Medicinal Botany
Govt. Siddha Medical College
Palayamkottai, Tirunelveli - 2.

GOVERNMENT SIDDHA MEDICAL COLLEGE

PALAYAMKOTTAI

SCREENING COMMITTEE

Candidate Reg No :

Department : Pothu Maruthuvam, Branch : I

This is to certify the dissertation topic "A Prospective open labeled randomized clinical study on **"THANDAGA VATHAM"** with evaluation of the trail drug **"VEPPAM PATTAI KUDINEER "** has been approved by the screening committee.

Branch	Department	Name	Signature
01	Pothu Maruthuvam	Dr.A.Manoharan MD (s) Professor	
02	Gunapadam	Dr.A.Kingsly MD (s) Associate Professor	
03	Sirappu Maruthuvam	Dr.A.S.Poongodikanthimathi MD (s) Professor	
04	Kuzhanthai Maruthuvam	Dr.D.K.Soundararajan MD (s) Professor	
05	NoiNadal	Dr.S.Victoria MD (s) Professor	
06	Nanju Nool Maruthuvam	Dr.M.Thiruthani MD (s) Professor	

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R.No.GSMC / 5676 / P&D / Res / IEC / 2014 **Date : 20.07.2016**

CERTIFICATE OF APPROVAL

Address of Ethical committee	Government Siddha Medical College Palayamkottai - 627002 Tirunelveli District
Principal investigator	Dr.L.Jensin Brintha M.D (s) First Year PG Dept of Pothu Maruthuvam Reg.No :
Supervisor	Dr.A.Manoharan M.D (s) Professor & Head of the Department
Guide	Dr.T.Komalavalli M.D (s) Associate Professor
Dissertation topic	A prospective open labeled randomized clinical trial on **"Thandaga Vatham" (Lumbar Spondylosis)** with evaluation of trial drug **"Veppam Pattai Kudineer"**
Document field	1. Protocol 2. Data Collection Form 3. Patient Information Sheet 4. Consent form
Clinical / Non Clinical trial Protocol	Clinical trial protocol - Yes
Informed consent document	Yes
Any other document	Case sheet, Investigation document
Date of IEC approval & it's Number	GSMC/3-IEC/2016-I-3/20.07.2016

We approve the trial to be conducted in its presented form.

The Institutional Ethical committee expects to be informed about the process report to be submitted to the IEC at least annually of the study, any SAE occurring in the course of the study and changes in the protocol and submission of final report.

Chairman
20/7/2016
(Prof.Dr.M.Logamanian PhD)

Member Secretary
20/7/16
(Prof. Dr.S.Victoria MD(s))

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Name	MRS.SHARMILA.	Patient ID	AS_VPI_CR_12793
Accession No	16_012793_182226	Age/Gender	38Y / Female
Referred By	Dr.GOVT.SIDDHA MEDICAL COLLEGE	Date	07-Mar-2018

X-RAY - LUMBAR SPINE AP & LATERAL VIEWS

OBSERVATION:

Anterior osteophytes noted in L4 & L5 vertebrae.

Sclerosis of bilateral sacroiliac joints.

The vertebrae is normal

The posterior elements are normal.

The alignment is normal.

Visualized intervertebral disc spaces are normal.

Para vertebral soft tissues are normal.

No abnormal radio opaque shadow is seen.

IMPRESSION:

- **Lumbar spondylosis.**
- **Bilateral sacroiliitis.**

DR. M. VENKATESAN., MDRD.,
CONSULTANT RADIOLOGIST.

AARTHI SCANS & LABS

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Name :	MRS. SHARMILA	Age/Sex :	37Y/F
Branch :	TUTICORIN	SID No :	18003979
Ref. By :	Dr. ASHIK AL MOHAMED MBBS DIP.IN.DIAB.,	SID Date :	07/12/2016

X RAY L.S.SPINE AP-LAT VIEWS

anterior osteophytes l4 and l5.

scalloping of lumbar end plates.

The vertebrae is normal

The posterior elements are normal.

The alignment is normal.

Visualized intervertebral disc spaces are normal.

Para vertebral soft tissues are normal.

Both sacro iliac joints are normal.

No abnormal radio opaque shadow is seen.

Impression:

- ***Lumbar spondylosis.***

DR. C.ARUN,MDRD.,
CONSULTANT RADIOLOGIST.

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For participating as ~~Resource Person~~ / Delegate in the Twenty First Workshop on

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*For **AYUSH Post Graduates & Researchers***

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6TH & 7TH APRIL 2018

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In recognition of the publication of the paper entitled **"An Insight into the traditional formulation Mathiiushna Rasayanam as per the Siddha text Yuuki vaithiya kaaviyum in the prevention of Infectious diseases"** published in IJCRMS Journal, Volume: 4, Issue: 6, Year: 2018.

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An Insight into the traditional formulation Mathiiushna Rasayanam as per the Siddha text Yuuki vaithiya kaaviyum in the prevention of Infectious diseases

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Abstract

Aim: The aim of the study is to examine the sample drug Mathiiushna Rasayanam through Microbial Limit Testing(Microbial Contamination Test, Specific Pathogen Testand the screening of antimicrobial activity by agar well diffusion method).

Methodology: Mathiiushna Rasayanam was prepared as per Siddha Materia Medica procedures.Extract of test sample Mathiiushna Rasayanam was prepared. Microbial Limit Testing-Total bacterial counting , total fungal counting and the screening of antimicrobial activity by agar well diffusion method were done.

Result: Thus the present study shows that Mathiiushna Rasayanam is free from microbial contamination. Both Gram positive and Gram negative bacteria were found to be high sensitive to Mathiiushna Rasayanam when compared to the standard drug Gentamycin (Broad spectrum).

Conclusion: It is concluded that the test drug Mathiiushna Rasayanam can be prescribed as the medicine for infectious disease due to pathogenic micro organism namely, *Escherichia coli*, *Klebsiella pneumoniae*, *Salmonella typhi*, *Pseudomonas aeuroginosa* and *Staphylococcus aureus* infections. This study also reveals that the Siddha literature evidence which was mentioned thousands years before the advent of modern science by Siddhars in Yuukivaithiyakaaviyum becomes true to this modern era.

Keywords: Siddha, Mathiiushna Rasayanam**,** Microbiological examination.

Introduction

The Siddha medicine is one of the oldest medical systems known to mankind. The word Siddha comes from the word Siddhi which means an object to be attained perfection or heavenly bliss. Siddha is focused to “Ashtamahasiddhi” that is the eight supernatural powers. Those who attained or achieved the “Ashtamahasiddhi” powers are known as Siddhars. Siddha medicine is claimed to revitalize and rejuvenate dysfunctional organs. The Siddha medicine given by practitioners includes leaves, flowers, fruit and various roots in a mixed basis.

Infectious disease, also known as transmissible disease or communicable disease is illness resulting from an pathogenic microbial infection. Dating back to Ancient Siddha literature, the Siddha formulations were found to be highly effective in prevention of the infectious diseases.

EVALUATION OF ANTI BACTERIAL ACTIVITY OF KODUPAAI CHOORANAM IN PREVENTING RESPIRATORY DISORDERS

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ABSTRACT:

A tremendous interest exists in global herbals and herbal based medicine is rapidly increasing commercial and scientific value. Till now,the concept of herbal combination is appreciated with its superior efficacy and lesser side effects in comparison with either single isolated constituents of herbal.The greater interaction between traditional systems of medicine with modern tools has opened up the possibility to insight antimicrobial activities of herbal preparations . Target Anti bacterial herbal drug selection plays a vital role and considered to be a heart of the new siddha drug discovery . In a great majority of cases, bacterial species are considered to be the most commonly isolated organisms . Dating back to Siddha literature, “Siddha materia medica” indicates Kodupaai herbal preparations for preventing Respiratory disorders. In this article, an attempt has been made to highlight the indepth scientific value and antibacterial sensitivity testing of the Siddha drug Kodupaai chooranam ,to ensure quality health.

Key words: Siddha, Kodupaai chooranam, Respiratory disorders, Antibacterial sensitivity.

Introduction:

The emergence of new infectious diseases, the resurgence of several infections that appeared to have been controlled and the increase in bacterial resistance have created the necessity for studies directed towards the development of new antimicrobials. In recent times, the search for potent antibacterial agents has been shifted to herbals. The anti microbial efficacy value attributed to some herbals is beyond belief. Therefore, there is a need to develop alternative antimicrobial drugs for the treatment of infectious diseases .As a result herbals are still recognised as the bedrock for the modern medicine to treat infectious diseases.